General

Guideline Title

Low back pain medical treatment guidelines.

Bibliographic Source(s)

Colorado Division of Workers' Compensation. Low back pain medical treatment guidelines. Denver (CO): Colorado Division of Workers' Compensation; 2014 Feb 3. 112 p.

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Regulatory Alert

FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- March 22, 2016 – Opioid pain medicines : The U.S. Food and Drug Administration (FDA) is warning about several safety issues with the entire class of opioid pain medicines. These safety risks are potentially harmful interactions with numerous other medications, problems with the adrenal glands, and decreased sex hormone levels. They are requiring changes to the labels of all opioid drugs to warn about these risks.

Recommendations

Major Recommendations

Note from the National Guideline Clearinghouse (NGC): This summary includes the treatment recommendations of the guideline. See the original guideline document for additional information on initial evaluation, diagnostic, and maintenance procedures for patients with low back pain and for further descriptions of the therapies discussed below.

Therapeutic Procedures—Non-operative

Before initiation of any therapeutic procedure, the authorized treating provider, employer, and insurer must consider these 4 important issues in the care of the injured worker.

First, patients undergoing therapeutic procedure(s) should be released or returned to modified or restricted duty during their rehabilitation at the earliest appropriate time. Refer to Section F.11., "Return to Work," in the original guideline document for detailed information.

Second, cessation and/or review of treatment modalities should be undertaken when no further significant subjective or objective improvement in the patient's condition is noted. If patients are not responding within the recommended duration periods, alternative treatment interventions, further diagnostic studies, or consultations should be pursued.

Third, providers should provide and document patient education. Before diagnostic tests or referrals for invasive treatment take place, the patient should be able to clearly articulate the goals of the intervention, the general side effects and associated risks, and the patient's agreement with the expected treatment plan.

Last, formal psychological or psychosocial evaluation should be performed on patients not making expected progress within 6 to 12 weeks following injury and whose subjective symptoms do not correlate with objective signs and tests.

Home therapy is an important component of therapy and may include active and passive therapeutic procedures as well as other modalities to assist in alleviating pain, swelling, and abnormal muscle tone.

The following procedures are listed in alphabetical order.

Acupuncture

There is good evidence that acupuncture, true or sham, is superior to usual care for the reduction of disability and pain in patients with chronic nonspecific low back pain, and that true and sham acupuncture are likely to be equally effective.

There is good evidence there is a likely, small clinical benefit of acupuncture for acute low back pain and it may be considered an alternative for some patients. There is good evidence that both acupuncture and sham acupuncture are superior to usual care without acupuncture for moderate short-term and mild long-term alleviation of low back pain, neck pain, and the pain of joint osteoarthritis. Another study provides good evidence that true acupuncture at traditional medians is marginally better than sham acupuncture with blunt needles in reducing pain, but effects on disability are unclear. In these studies 5 to 15 treatments were provided. Comparisons of acupuncture and sham acupuncture have been inconsistent, and the advantage of true over sham acupuncture has been small in relation to the advantage of sham over no acupuncture.

Acupuncture is recommended for subacute or chronic pain patients who are trying to increase function and/or decrease medication usage and have an expressed interest in this modality. It is also recommended for subacute or acute low back pain for patients who cannot tolerate non-steroidal anti-inflammatory drugs (NSAIDs) or other medications. Acupuncture is not the same procedure as dry needling for coding purposes; however, some acupuncturists may use acupuncture treatment for myofascial trigger points. Dry needling is performed specifically on myofascial trigger points. Refer to Section F.4.h., "Trigger Point Injections and Dry Needling Treatment," in the original guideline document.

Credentialed practitioners with experience in evaluation and treatment of chronic pain patients must perform acupuncture evaluations.

Acupuncture

This is the insertion and removal of filiform needles to stimulate acupoints (acupuncture points). Needles may be inserted, manipulated, and retained for a period of time. Acupuncture has a variety of possible physiologic actions, but their relevance to the clinical response is speculative. For example, one crossover trial measured increasing palmar blood flow and increased nitric oxide synthase activity in arms which had had acupuncture, but this observation may have no bearing on actual analgesic effects.

Indications include joint pain, joint stiffness, soft tissue pain and inflammation, paresthesia, post-surgical pain relief, muscle spasm, and scar tissue pain.

Acupuncture with Electrical Stimulation

The use of electrical current (micro-amperage or milli-amperage) on the needles at the acupuncture site. It is used to increase effectiveness of the needles by continuous stimulation of the acupoint. Physiological effects (depending on location and settings) can include endorphin release for pain relief, reduction of inflammation, increased blood circulation, analgesia through interruption of pain stimulus, and muscle relaxation.

It is indicated to treat chronic pain conditions, radiating pain along a nerve pathway, muscle spasm, inflammation, scar tissue pain, and pain located in multiple sites.

Other Acupuncture Modalities

Acupuncture treatment is based on individual patient needs and therefore treatment may include a combination of procedures to enhance treatment effect. Other procedures may include the use of heat, soft tissue manipulation/massage, and exercise. Refer to Sections F.12.g., "Therapeutic Exercise," F.13.g., "Massage – Manual or Mechanical," and F.13.k., "Superficial Heat and Cold Therapy (excluding Infrared Therapy)," in the original guideline document for a description of these adjunctive acupuncture modalities and time frames.

Total Time Frames for Acupuncture and Acupuncture with Electrical Stimulation

Time frames are not meant to be applied to each of the above sections separately. The time frames are to be applied to all acupuncture treatments regardless of the type or combination of therapies being provided. Refer to the original guideline document for time to produce effect, frequency, and optimum and maximum duration of treatments.

Any of the above acupuncture treatments may extend longer if objective functional gains can be documented and when symptomatic benefits facilitate progression in the patient's treatment program. Treatment beyond 15 treatments must be documented with respect to need and the ability to facilitate positive symptomatic and functional gains. Such care should be re-evaluated and documented with each series of treatments. All treatments should be accompanied by active therapy.

Biofeedback

Biofeedback is a form of behavioral medicine that helps patients learn self-awareness and self-regulation skills for the purpose of gaining greater control of their physiology, such as muscle activity, brain waves, and measures of autonomic nervous system activity. Stress-related psycho-physiological reactions may arise as a reaction to organic pain and in some cases may cause pain. Electronic instrumentation is used to monitor the targeted physiology and then displayed or fed back to the patient visually, auditorily, or tactilely, with coaching by a biofeedback specialist. There is good evidence that biofeedback or relaxation therapy is equal in effect to cognitive behavioral therapy for chronic low back pain.

Indications for biofeedback include cases of musculoskeletal injury, in which muscle dysfunction or other physiological indicators of excessive or prolonged stress response affects and/or delays recovery. Other applications include training to improve self-management of pain, anxiety, panic, anger or emotional distress, opioid withdrawal, insomnia/sleep disturbance, and other central and autonomic nervous system imbalances. Biofeedback is often utilized for relaxation training. Mental health professionals may also utilize it as a component of psychotherapy, where biofeedback and other behavioral techniques are integrated with psychotherapeutic interventions. Biofeedback is often used in conjunction with physical therapy or medical treatment.

Please refer to the original guideline document for recognized types of biofeedback.

Psychologists or psychiatrists who provide psycho-physiological therapy, which integrates biofeedback with psychotherapy, should be either Biofeedback Certification International Alliance (BCIA) certified or practicing within the scope of their training. All non-licensed health care providers of biofeedback for chronic pain patients must be BCIA certified and shall have their biofeedback treatment plan approved by the authorized treating psychologist or psychiatrist. Biofeedback treatment must be done in conjunction with the patient's psychosocial intervention. Biofeedback may also be provided by health care providers who follow a set treatment and educational protocol. Such treatment may utilize standardized material or relaxation tapes.

Refer to the original guideline document for time to produce effect, frequency, and optimum and maximum duration of treatments.

Injections–Spinal Therapeutic

Description

Therapeutic spinal injections are established procedures. Regarding short-term benefits from injections, there is strong evidence that epidural steroid injections have a small average short term benefit for leg pain and disability for those with sciatica. Additionally, specific to transforaminal injections, there is good evidence that the addition of steroids to a transforaminal bupivacaine injection has a small effect on patient reported pain and disability.

Regarding long term benefit from injections, there is strong evidence that epidural steroid injections (ESI) do not, on average, provide clinically meaningful long-term improvements in leg pain, back pain, or disability in patients with sciatica (lumbar radicular pain or radiculopathy).

Conversely, there is some evidence that the addition of steroids to a transforaminal bupivacaine injection may reduce the frequency of surgery in the first year after treatment in patients with neurologic compression and corresponding imaging findings who also are strong candidates for surgery and have completed 6 weeks of therapy without adequate benefit. There is some evidence that the benefits for the non-surgical group persisted for at least 5 years in most patients, regardless of the type of block given. An additional study provides some evidence that after 6 weeks of

conservative therapy for large herniated discs, an epidural injection may be attempted, as it does not compromise the results of a discectomy at a later date. One half of the patients in this study who were randomized to ESIs did not have surgery and this benefit persisted. Because this study did not have a control group that received neither treatment, nor a group which received injections without steroids, one cannot make definite conclusions regarding the efficacy of ESI injections in this setting.

There is strong evidence that ESI has no short or long term benefit for low back pain. A high quality meta-analysis provides additional good evidence against the use of lumbar facet or epidural injections for relief of non-radicular low back pain. Facet injections have very limited therapeutic or diagnostic use. Refer to Section F.3.e., "Zygapophyseal (Facet) Injections," in the original guideline document.

In summary, there is no proven benefit from adding steroids to local anesthetic spinal injections for most injections, with the possible exception of patients who are strong candidates for surgery based on a herniated disc and clear nerve impingement. However, steroids are currently used routinely in spinal injections due to a presumed physiologic effect.

Therapeutic spinal injections have not been proven to change the long-term course of most patients with spinal pain. They have a limited role in treatment and should be used in only a small subset of patients where the criteria below have been clearly met. Refer to the specific injections as described in this section for indications.

Therapeutic injections should only be used after diagnostic injections and imaging studies have established pathology which has not clinically improved after active engagement (6–8 weeks) of physical therapy and in patients who otherwise qualify for more invasive procedures and may need injections because they do not wish to proceed to surgery.

The purpose of spinal injections is to facilitate active therapy by providing short-term relief through reduction of pain and inflammation. All patients must commit to continuing appropriate exercise with functionally directed rehabilitation usually beginning within 7 days, at the injectionist's discretion. Active treatment, which patients should have had prior to injections, will frequently require a repeat of the sessions previously ordered (refer to Section F.12., "Therapy–Active"). Injections, by themselves, are not likely to provide long-term relief. Rather, active rehabilitation with modified work achieves long-term relief by increasing active range of motion (ROM), strength, and stability.

Informed decision making should also be documented for injections and all invasive procedures. This must include a thorough discussion of the pros and cons of the procedure and the possible complications as well as the natural history of the identified diagnosis. The purpose of spinal injections, as well as surgery, is to facilitate active therapy by providing short-term relief through reduction of pain. Patients should be encouraged to express their personal goals, outcome expectations and desires from treatment as well as any personal habits or traits that may be impacted by procedures or their possible side effects. All patients must commit to continuing appropriate exercise with functionally directed rehabilitation usually beginning within 7 days, at the injectionist's discretion. Since most patients with these conditions will improve significantly over time, without invasive interventions, patients must be able to make well-informed decisions regarding their treatment. All injections must be accompanied by active therapy.

Special Requirements for Spinal Therapeutic Injections

Since multi-planar fluoroscopy during procedures is required to document technique and needle placement, an experienced physician should perform the procedure. Injection of contrast dye to assure correct needle placement is required to verify the flow of medication. Permanent images are required to verify needle placement. Unnecessary fluoroscopy procedures should be avoided due to the radiation exposure contributing to cancer risk.

Complications

General complications of therapeutic injections may include transient neurapraxia, nerve injury, infection, headache, urinary retention, vasovagal effects, epidural hematoma, permanent neurologic damage, dural perforation, cerebrospinal fluid (CSF) leakage, and spinal meningeal abscess. There are reports of direct spinal cord injury due to needle trauma. Permanent paresis, anaphylaxis, arachnoiditis, and death have been rarely reported with the use of epidural steroids.

With steroid injections, there may be a dose-dependent suppression of the hypothalamic-pituitary-adrenal axis lasting between one and three months. Case reports of Cushing Syndrome, hypopituitarism and growth hormone deficiency have been tied to systemic absorption of intra-articular and epidural steroid injections.

Cushing's syndrome has been reported from serial occipital nerve injections and paraspinal injections. Several cases of spinal epidural lipomatosis have also been reported that may have been caused or exacerbated by spinal steroid injections.

Morning cortisol measurements may be ordered prior to repeat steroid injections or initial spinal steroid injection when the patient has received multiple previous steroid joint injections.

A well-controlled, large retrospective cohort study found that individuals with the same risk factors for osteoporotic fractures were 20% more likely to suffer a lumbar fracture if they had an epidural steroid injection. The risk increased with multiple injections.

Contraindications

Absolute contraindications to therapeutic injections include: (a) bacterial infection – systemic or localized to region of injection, (b) bleeding diatheses, (c) hematological conditions, (d) pain of 3 points or less on a 10-point VAS measurement at the time of injection, (e) possible pregnancy, and (f) poorly controlled diabetes mellitus for steroid injections.

Relative contraindications to therapeutic injections may include: allergy to contrast, somatization disorders, poorly controlled congestive heart failure (CHF) for steroid injections, risk factors for osteoporosis and uncontrolled hypertension. Drugs affecting coagulation frequently require restriction from use.

The following are in alphabetical order:

Epidural Steroid Injection (ESI)

Description

Epidural steroid injections are injections of corticosteroid into the epidural space. Purported to reduce pain and inflammation in the acute or sub-acute phases of injury, restoring range of motion and, thereby, facilitating progress in more active treatment programs.

Regarding short-term benefits from injections, there is strong evidence that epidural steroid injections have a small average short-term benefit for leg pain and disability for those with sciatica. Additionally, specific to transforaminal injections, there is good evidence that the addition of steroids to a transforaminal bupivacaine injection has a small effect on patient reported pain and disability.

Regarding long-term benefit from injections, there is strong evidence that ESIs do not, on average, provide clinically meaningful long-term improvements in leg pain, back pain, or disability in patients with sciatica (lumbar radicular pain or radiculopathy).

Conversely, there is some evidence that the addition of steroids to a transforaminal bupivacaine injection may reduce the frequency of surgery in the first year after treatment in patients with neurologic compression and corresponding imaging findings, who are strong candidates for surgery and have completed 6 weeks of therapy without adequate benefit. There is some evidence that the benefits for the non-surgical group persisted for at least 5 years in most patients, regardless of the type of block given. An additional study provides some evidence that after 6 weeks of conservative therapy for large herniated discs, an epidural injection may be attempted as it does not compromise the results of a discectomy at a later date. One half of the patients in this study who were randomized to ESIs did not have surgery and this benefit persisted. Because this study did not have a control group who received neither treatment, nor a group which received injections without steroids, one cannot make definite conclusions regarding the efficacy of ESI injections in this setting.

There is strong evidence that ESI has no short or long term benefit for low back pain. A high quality meta-analysis provides additional good evidence against the use of lumbar facet or epidural injections for relief of non-radicular low back pain. Facet injections have very limited therapeutic or diagnostic use (refer to Section F.3., "Injections–Spinal Therapeutic," in the original guideline document).

There is some evidence that patients who smoke respond less well to non-operative spine care and that quitting smoking results in greater improvement.

In summary, there is no proven benefit from adding steroids to local anesthetic spinal injections for most injections, with the possible exception of patients who are strong candidates for surgery based on a herniated disc and clear nerve impingement. However, steroids are currently used routinely in spinal injections due to a presumed physiologic effect.

Needle Placement

Multi-planar fluoroscopic imaging is required for all epidural steroid injections. Injection of contrast dye to assure correct needle placement is required to verify the flow of medication. Permanent images are required to verify needle placement.

Indications

There is strong evidence that epidural injections do not improve long-term outcomes for populations of patients who were diagnosed as having lumbar radicular pain. There is some evidence they may decrease the need for surgery among candidates for nerve decompression and discectomy. In addition, patients can suffer long-term morbidity from injections, although these complications are rare. Therefore, injections are allowed for only a small subset of patients with radicular findings. They may be used for patients who are having significant pain that is interfering with daily functions and the active therapy necessary for recovery despite medical pain management and active therapy. All injections should be

preceded by a magnetic resonance imaging (MRI) or a computed tomography (CT) scan.

See the original guideline document for sets of patients that may have therapeutic epidural injections, when diagnostic epidural injections are positive.

Intradiscal Steroid Injections

There is some evidence that intradiscal steroid injection is unlikely to relieve pain or provide functional benefit in patients with non-radicular back pain therefore, they are not recommended.

Intradiscal injections of other substances such as bone marrow, stem cells, are not recommended at this time due to lack of evidence and possible complications.

Sacroiliac (SI) Joint Injection

Description

A generally accepted injection of local anesthetic in an intra-articular fashion into the SI joint under fluoroscopic guidance. May include the use of corticosteroids. Long-term therapeutic effect has not yet been established.

Needle Placement

Multi-planar fluoroscopic imaging is required for all steroid injections. Injection of contrast dye to assure correct needle placement is required to verify the flow of medication. Permanent images are required to verify needle placement.

Indications

Since these procedures are invasive, less invasive or non-invasive procedures should be considered first. All injections should be preceded by an MRI or a CT scan. Selection of patients, choice of procedure, and localization of the level for injection should be determined by clinical information indicating strong suspicion for pathologic condition(s), compatible MRI findings, and the source of pain symptoms. To qualify for an injection the patient must have at least 3 positive physical exam maneuvers (e.g., Patrick's sign, Faber's test, Gaenslen, distraction or gapping, or compression test). Blocks are only appropriate if the patient is eligible for increased therapy, such as a rhizotomy, based on the results of the block.

Informed decision making should also be documented for injections and all invasive procedures. This must include a thorough discussion of the pros and cons of the procedure and the possible complications as well as the natural history of the identified diagnosis. The purpose of spinal injections, as well as surgery, is to facilitate active therapy by providing short-term relief through reduction of pain. Patients should be encouraged to express their personal goals, outcome expectations and desires from treatment as well as any personal habits or traits that may be impacted by procedures or their possible side effects. All patients must commit to continuing appropriate exercise with functionally directed rehabilitation usually beginning within 7 days, at the injectionist's discretion. Since most patients with these conditions will improve significantly over time without invasive interventions, patients must be able to make well-informed decisions regarding their treatment. All injections must be accompanied by active therapy.

It is obligatory that sufficient data be accumulated by the examiner performing this procedure such that the value of the procedure is evident to other reviewers. This entails documentation of patient response regarding the degree and type of response to specific symptoms. The examiner should identify three or four measurable provocative physical exam maneuvers (e.g., Patrick's sign, Faber's test, Gaenslen, distraction or gapping, or compression test), and physical functions, which are currently impaired and can be objectively reassessed 30 minutes or more after the injection. A successful block requires documentation of positive functional changes by trained medical personnel experienced in measuring range of motion or assessing activity performance. The evaluator should be acquainted with the patient, in order to determine pre and post values, and preferably unaffiliated with the injectionist's office. Qualified evaluators include nurses, physician assistants, medical assistants, therapists, or non-injectionist physicians. To be successful the results should occur within the expected time frame and there should be pain relief of approximately 80% demonstrated by pre and post Visual Analog Scale (VAS) scores. Examples of functional changes may include sitting, walking, and lifting. Additionally, a prospective patient completed pain diary must be recorded as part of the medical record that documents response hourly for a minimum requirement of the first 8 hours post injection or until the block has clearly worn off and preferably for the week following an injection. The diary results should be compared to the expected duration of the local anesthetic phase of the procedure. Responses must be identified as to specific body part (e.g., low back, leg pain). The practitioner must identify the local anesthetic used and the expected duration of response for assessment purposes.

Light sedation and pain relief may be needed for some patients requiring therapeutic injection. Refer to the original guideline document for time to

produce effect, frequency, and optimum and maximum duration of treatments.

Transforaminal Injection with Etanercept

Description

Transforaminal injection with a tumor necrosis factor alpha inhibitor is thought to decrease the inflammatory agents which may be associated with the pathophysiology of lumbar radicular pain from a herniated disc.

It is not recommended due to the results of a study which showed no advantage over steroids or saline injections.

Zygapophyseal (Facet) Injection

Description

This is an accepted intra-articular or pericapsular injection of local anesthetic and corticosteroid with very limited uses. There is no justification for a combined facet and medial branch block. A high quality meta-analysis provides good evidence against the use of lumbar facet or epidural injections for relief of non-radicular low back pain. Facet injections have very limited use (refer to Section F.3.a., "Injections–Spinal Therapeutic," in the original guideline document).

Needle Placement

Multi-planar fluoroscopic imaging is required for all steroid injections. Injection of contrast dye to assure correct needle placement is required to verify the flow of medication. Permanent images are required to verify needle placement.

Indications

Patients with pain 1) suspected to be facet in origin based on exam findings and 2) affecting activity; OR patients who have refused a rhizotomy and appear clinically to have facet pain; OR patients who have facet findings with a thoracic component. The physician should document the findings which, for lumbar and cervical spine, consist of pain with extension and lateral bending with referral patterns consistent with the expected pathologic level. In these patients, facet injections may be occasionally useful in facilitating a functionally-directed rehabilitation program and to aid in identifying pain generators. Patients with recurrent pain should be evaluated with more definitive diagnostic injections, such as medial nerve branch injections, to determine the need for a rhizotomy. Because facet injections are not likely to produce long-term benefit by themselves and are not the most accurate diagnostic tool, they should not be performed at more than 2 levels, unilaterally or bilaterally. Due to the lack of proof that these injections improve outcome, prior authorization is required. A high quality meta-analysis provides good evidence against the use of lumbar facet or epidural injections for relief of non-radicular low back pain. All injections should be preceded by an MRI or a CT scan.

Light sedation and pain relief may be needed for some patients requiring therapeutic injection. Refer to the original guideline document for time to produce effect, frequency, and optimum and maximum duration of treatments.

Injections–Other (Including Radiofrequency [RF])

The following are in alphabetical order:

Botulinum Toxin Injections

Description

Used to temporarily weaken or paralyze muscles. These injections may reduce muscle pain in conditions associated with spasticity or dystonia. Neutralizing antibodies develop in at least 4% of patients treated with botulinum toxin type A, rendering it ineffective. Several antigenic types of botulinum toxin have been described.

There is a lack of adequate evidence supporting the use of these injections to lumbar musculature for the relief of isolated low back pain. There is insufficient evidence to support its use for longer-term pain relief of other myofascial trigger points and it is likely to cause muscle weakness or atrophy if used repeatedly. Examples of such consequences include subacromial impingement, as the stabilizers of the shoulder are weakened by repeated injections of trigger points in the upper trapezii. Therefore, it is not recommended for use for low back pain or other myofascial trigger points.

They may be used for chronic piriformis syndrome. There is some evidence to support injections for electromyographically proven piriformis syndrome. Prior to consideration of botulinum toxin injection for piriformis syndrome, patients should have had marked (80% or better) but temporary improvement, verified with demonstrated improvement in functional activities, from three separate trigger point injections. To be a

candidate for botulinum toxin injection for piriformis syndrome, patients should have had symptoms return to baseline or near baseline despite an appropriate stretching program after trigger point injections. Botulinum toxin injections of the piriformis muscle should be performed by a physician experienced in this procedure and utilize either ultrasound, fluoroscopy, or EMG needle guidance. Botulinum toxin should be followed by limb strengthening and reactivation.

Indications

Piriformis syndrome established by three trigger point injections and unrelieved by other therapy.

Epiduroscopy and Epidural Lysis of Adhesions

This is a controversial and investigational treatment of low back pain. It involves the introduction of a fiberoptic endoscope into the epidural space via the sacral hiatus. With cephalad advancement of the endoscope under direct visualization, the epidural space is irrigated with saline. Adhesiolysis may be done mechanically with a fiberoptic endoscope. The saline irrigation is performed with or without epiduroscopy and is intended to distend the epidural space in order to obtain an adequate visual field. It is designed to produce lysis of adhesions, which are conjectured to produce symptoms due to traction on painful nerve roots. Saline irrigation is associated with risks of elevated pressures which may impede blood flow and venous return, possibly causing ischemia of the cauda equina and retinal hemorrhage. Other complications associated with instrumented lysis include catheter shearing, need for catheter surgical removal, infection (including meningitis), hematoma, and possible severe hemodynamic instability during application. Although epidural adhesions have been postulated to cause chronic low back pain, studies have failed to find a significant correlation between the level of fibrosis and pain or difficulty functioning. Studies of epidural lysis demonstrate no transient pain relief from the procedure. Given the low likelihood of a positive response, the additional costs and time requirement, and the possible complications from the procedure, epiduroscopy, or mechanical lysis, is not recommended.

Epiduroscopy-directed steroid injections are also not recommended because there is no evidence to support an advantage in using an epiduroscope with steroid injections.

Prolotherapy

Also known as sclerotherapy, prolotherapy consists of a series of injections of hypertonic dextrose, with or without glycerine and phenol, into the ligamentous structures of the low back. Its proponents claim that the inflammatory response to the injections will recruit cytokine growth factors involved in the proliferation of connective tissue, stabilizing the ligaments of the low back when these structures have been damaged by mechanical insults.

There is good evidence that prolotherapy alone is not an effective treatment for chronic low back pain. There is some evidence that prolotherapy of the SI joint is longer lasting, up to 15 months, than intra-articular steroid injections. The study was relatively small and long-term blinding was unclear, however all injections were done under fluoroscopic guidance. Indications included an 80% reduction in pain from an SI joint injection with local anesthetic, as well as physical findings of SI joint dysfunction. Lasting functional improvement has not been shown and approximately three injections were required. The injections are invasive, and may be painful to the patient. The use of prolotherapy for low back pain is generally not recommended, as the majority of patients with SI joint dysfunction will do well with a combination of active therapy and manipulation and not require prolotherapy. However, it may be used in select patients. Prolotherapy is not recommended for other non-specific back pain.

RF Ablation–Dorsal Nerve Root Ganglion

Due to the combination of possible adverse side effects, time limited effectiveness, and mixed study results, this treatment is not recommended (refer to the NGC summary of the Colorado Division of Workers' Compensation Chronic pain disorder medical treatment guidelines.

RF Denervation–Medial Branch Neurotomy/Facet Rhizotomy

Description

A procedure designed to denervate the facet joint by ablating the corresponding sensory medial branches. Continuous percutaneous RF is the method generally used. Pulsed RF should not be used as it may result in incomplete denervation. Cooled RF is generally not recommended due to current lack of evidence.

There is good evidence in the lumbar spine that carefully selected patients who had 80% relief with medial branch controlled blinded blocks and then had RF neurotomy will have improved pain relief over 6 months and decreased impairment compared to those than those who had sham procedures. Generally pain relief lasts 7 to 9 months and repeat RF neurotomy can be successful and last longer. RF neurotomy is the procedure of choice over alcohol, phenol, or cryoablation. Precise positioning of the probe using fluoroscopic guidance is required because the maximum

effective diameter of the device is a 5 x 8 millimeter oval. Permanent images should be recorded to verify placement of the device.

Needle Placement

Multi-planar fluoroscopic imaging is required for all injections. Injection of contrast dye to assure correct needle placement is required to verify the flow of medication. Permanent images are required to verify needle placement.

Indications

Those patients with proven, significant, facetogenic pain. A minority of low back patients would be expected to qualify for this procedure. This procedure is not recommended for patients with multiple pain generators or involvement of more than 3 levels of medial branch nerves.

All patients should continue appropriate exercise with functionally directed rehabilitation. Active treatment, which patients will have had prior to the procedure, will frequently require a repeat of the sessions previously ordered (refer to Section F.13., "Therapy–Active," in the original guideline document).

It is obligatory that sufficient data be accumulated by the examiner performing this procedure such that the value of the medial branch block is evident to other reviewers. This entails documentation of patient response regarding the degree and type of response to specific symptoms. As recommended by the International Spine Intervention Society (ISIS) guidelines, the examiner should identify three or four measurable physical functions, which are currently impaired and can be objectively reassessed 30 minutes or more after the injection. A successful block requires documentation of positive functional changes by trained medical personnel experienced in measuring range of motion or assessing activity performance. The evaluator should be acquainted with the patient, in order to determine pre and post values, and preferably unaffiliated with the injectionist's office. Qualified evaluators include nurses, physician assistants, medical assistants, therapists, or non-injectionist physicians. To be successful the results should occur within the expected time frame and there should be pain relief of approximately 80% demonstrated by pre and post VAS scores. Examples of functional changes may include sitting, walking, and lifting. Additionally, a prospective patient completed pain diary must be recorded as part of the medical record that documents response hourly for a minimum requirement of the first 8 hours post injection or until the block has clearly worn off and preferably for the week following an injection. The diary results should be compared to the expected duration of the local anesthetic phase of the procedure. Responses must be identified as to specific body part (e.g., low back, leg pain). The practitioner must identify the local anesthetic used and the expected duration of response for assessment purposes.

In almost all cases, this will mean a reduction of pain to 1 or 2 on the 10-point VAS correlated with functional improvement. The patient should also identify activities of daily living (ADLs) (which may include measurements of ROM) that are impeded by their pain and can be observed to document objective functional improvement in the clinical setting. Ideally, these activities should be assessed throughout the observation period for function. The observer should not be the physician who performed the procedure. It is suggested that this be recorded on a form similar to ISIS recommendations.

A separate comparative block on a different date should be performed to confirm the level of involvement prior to the rhizotomy. A comparative block uses anesthetics with varying lengths of activity. Medial branch blocks are probably not helpful to determine the likelihood of success for spinal fusion.

The success rate of RF neurotomy is likely to decrease with lower percentages of pain relief from a medial branch block.

Informed decision making should also be documented for injections and all invasive procedures.

Refer to the original guideline document for information regarding complications, post-procedure therapy, and requirements for repeat RF neurotomy.

RF Denervation–SI Joint Cooled

This procedure requires neurotomy of multiple nerves, L5 dorsal ramus, and lateral branches of S1-S3 under C-arm fluoroscopy. There is good evidence that cooled RF neurotomy performed in a highly selected population results in better pain relief and functional gains than a sham procedure. The benefits persisted for 9 months. Approximate half of the patients had benefits initially and approximately half of those reported the pain was completely relieved.

Needle Placement

Multi-planar fluoroscopic imaging is required for all steroid injections. Injection of contrast dye to assure correct needle placement is required to verify the flow of medication. Permanent images are required to verify needle placement.

Refer to the original guideline document for information regarding indications.

Complications

Damage to sacral nerve roots – issues with bladder dysfunction etc. Bleeding, infection, or neural injury. The clinician must be aware of the risk of developing a localized neuritis, or rarely, a deafferentation centralized pain syndrome as a complication of this and other neuroablative procedures.

Post-procedure therapy–active therapy: Implementation of a gentle aerobic reconditioning program (e.g., walking) and back education within the first post-procedure week, barring complications. Instruction and participation in a long-term home-based program of ROM, core strengthening, postural or neuromuscular re-education, endurance, and stability exercises should be accomplished over a period of four to ten visits post-procedure. Patients who are unwilling to engage in this therapy should not receive this procedure.

Requirements for repeat RF SI joint neurotomy: In some cases pain may recur. Successful RF Neurotomy usually provides from 6 to 18 months of relief. Repeat neurotomy should only be performed if the initial procedure resulted in improved function for 6 months.

Due to denervation of spinal musculature repeated rhizotomies should be limited.

Transdiscal Biacuplasty

Description: Cooled RF procedure intended to coagulate fissures in the disc and surrounding nerves which could be pain generators.

It is not recommended due to lack of published data demonstrating effectiveness.

Trigger Point Injections and Dry Needling Treatment

Description

Trigger point injections are a generally accepted treatment. Trigger point treatment can consist of dry needling or injection of local anesthetic, with or without corticosteroid, into highly localized, extremely sensitive bands of skeletal muscle fibers that produce local and referred pain when activated. Medication is injected in a four-quadrant manner in the area of maximum tenderness. Injection efficacy can be enhanced if injections are immediately followed by myofascial therapeutic interventions, such as vapo-coolant spray and stretch, ischemic pressure massage (myotherapy), specific soft tissue mobilization and physical modalities. There is conflicting evidence regarding the benefit of trigger point injections. A truly blinded study comparing dry needle treatment of trigger points is not feasible. There is no evidence that injection of medications improves the results of trigger-point injections. Needling alone may account for some of the therapeutic response. Needling must be performed by practitioners with the appropriate credentials in accordance with state and other applicable regulations.

There is no indication for conscious sedation for patients receiving trigger point injections. The patient must be alert to help identify the site of the injection.

Indications

Trigger point injections may be used to relieve myofascial pain and facilitate active therapy and stretching of the affected areas. They are to be used as an adjunctive treatment in combination with other treatment modalities such as active therapy programs. Trigger point injections should be utilized primarily for the purpose of facilitating functional progress. Patients should continue in an aggressive aerobic and stretching therapeutic exercise program as tolerated throughout the time period they are undergoing intensive myofascial interventions. Myofascial pain is often associated with other underlying structural problems and any abnormalities need to be ruled out prior to injection.

Trigger point injections are indicated in those patients where well circumscribed trigger points have been consistently observed, demonstrating a local twitch response, characteristic radiation of pain pattern and local autonomic reaction, such as persistent hyperemia following palpation. Generally, these injections are not necessary unless consistently observed trigger points are not responding to specific, noninvasive, myofascial interventions within approximately a 6-week time frame. However, trigger point injections may be occasionally effective when utilized in the patient with immediate, acute onset of low back pain.

Complications

Potential but rare complications of trigger point injections include infection, pneumothorax, anaphylaxis, penetration of viscera, neurapraxia, and neuropathy. If corticosteroids are injected in addition to local anesthetic, there is a risk of local myopathy. Severe pain on injection suggests the possibility of an intraneural injection, and the needle should be immediately repositioned.

Refer to the original guideline document for time to produce effect, frequency, and optimum and maximum duration of treatments.

Interdisciplinary Rehabilitation Programs

This is the gold standard of treatment for individuals with low back pain who have not responded to less intensive modes of treatment. There is good evidence that interdisciplinary programs which include screening for psychological issues, identification of fear-avoidance beliefs and treatment barriers, and establishment of individual functional and work goals will improve function and decrease disability. These programs should assess the impact of pain and suffering on the patient's medical, physical, psychological, social, and/or vocational functioning. In general, interdisciplinary programs evaluate and treat multiple and sometimes irreversible conditions, including, but not limited to: painful musculoskeletal, neurological, and other chronic pain conditions and psychological issues; drug dependence, abuse, or addiction; high levels of stress and anxiety; failed surgery; and pre-existing or latent psychopathology. The number of professions involved on the team in a chronic pain program may vary due to the complexity of the needs of the person served. The Division recommends consideration of referral to an interdisciplinary program within 6 months post-injury in patients with delayed recovery, unless successful surgical interventions or other medical and/or psychological treatment complications intervene.

Chronic pain patients need to be treated as outpatients within a continuum of treatment intensity. Outpatient chronic pain programs are available with services provided by a coordinated interdisciplinary team within the same facility (formal) or as coordinated among practices by the authorized treating physician (informal). Formal programs are able to provide a coordinated, high-intensity level of services and are recommended for most chronic pain patients who have received multiple therapies during acute management.

Patients with addiction problems, high-dose opioid use, or use of other drugs of abuse may require inpatient and/or outpatient chemical dependency treatment programs before or in conjunction with other interdisciplinary rehabilitation. Guidelines from the American Society of Addiction Medicine are available and may be consulted relating to the intensity of services required for different classes of patients in order to achieve successful treatment.

Informal interdisciplinary pain programs may be considered for patients who are currently employed, those who cannot attend all-day programs, those with language barriers, or those living in areas not offering formal programs. Before treatment has been initiated, the patient, physician, and insurer should agree on treatment approach, methods, and goals. Generally, the type of outpatient program needed will depend on the degree of impact the pain has had on the patient's medical, physical, psychological, social, and/or vocational functioning.

When referring a patient for formal outpatient interdisciplinary pain rehabilitation, an occupational rehabilitation program, or an opioid treatment program, the Division recommends the program meets the criteria of the Commission on Accreditation of Rehabilitation Facilities (CARF).

Inpatient pain rehabilitation programs are rarely needed but may be necessary for patients with any of the following conditions: (a) high risk for medical instability; (b) moderate-to-severe impairment of physical/functional status; (c) moderate-to-severe pain behaviors; (d) moderate impairment of cognitive and/or emotional status; (e) dependence on medications from which he/she needs to be withdrawn; and (f) the need for 24-hour supervised nursing.

Whether formal or informal programs, they should be comprised of the following dimensions:

- Communication
- Documentation
- Treatment modalities
- Therapeutic exercise programs
- Return-to-work
- Patient education
- Psychosocial evaluation and treatment
- Vocational assistance

Interdisciplinary programs are characterized by a variety of disciplines that participate in the assessment, planning, and/or implementation of the treatment program. These programs are for patients with greater levels of perceived disability, dysfunction, de-conditioning, and psychological involvement. Programs should have sufficient personnel to work with the individual in the following areas: behavioral, functional, medical, cognitive, pain management, psychological, social, and vocational.

Refer to the original guideline document for more information regarding formal and informal interdisciplinary rehabilitation programs.

Medications

Use in the treatment of low-back injuries is appropriate for controlling acute and chronic pain and inflammation. Use of medications will vary widely due to the spectrum of injuries, from simple strains to post-surgical healing. A thorough medication history, including use of alternative and over-the-counter medications, should be performed at the time of the initial visit and updated periodically. Treatment for pain control is initially accomplished with acetaminophen and/or NSAIDs. The patient should be educated regarding the interaction of prescription and over-the-counter

medications as well as the contents of over-the-counter herbal products. The medication lists below do not provide complete information on side effects or drug interactions. Providers should seek information from other sources for details. The following are listed in alphabetical order. Refer to the original guideline document for additional information about each of the medications listed below, including optimal and maximum duration of treatment for recommended medications.

- Acetaminophen
- Antibiotics for chronic pain secondary to disc herniation
- Intravenous steroids
- Glucosamine (not recommended for chronic lumbar spinal or non-joint pain)
- Muscles relaxants
- NSAIDs (chronic use of NSAIDs is generally not recommended due to increased risk of cardiovascular events and GI bleeding)
- Opioids
- Oral steroids (not generally recommended)
- Psychotropic/anti-anxiety/hypnotic agents
- Tramadol (not generally recommended for those with prior opioid addiction)

Orthotics

Refer to the original guideline document for information on the following:

- Foot orthoses and inserts
- Lumbar support devices
- Lumbar corsets and back belts
- Lumbosacral bracing

Education/Informed Decision Making

Education/informed decision making of the patient and family, as well as the employer, insurer, policy makers and the community should be the primary emphasis in the treatment of low back pain and disability. Unfortunately, practitioners often think of education and informed decision making last, after medications, manual therapy, and surgery.

Informed decision making is the hallmark of a successful treatment plan. In most cases the continuum of treatment from the least invasive to the most invasive (e.g., surgery) should be discussed. The intention is to find the treatment along this continuum which most completely addresses the condition. Patients should identify their personal functional goals of treatment at the first visit. It is recommended that specific individual goals are articulated at the beginning of treatment as this is likely to lead to increased patient satisfaction above that achieved from improvement in pain or other physical function. There is some evidence that a 2 day course focusing on the biopsychosocial model with an emphasis on the goals of returning to usual activities and fitness is as effective in reducing disability as six manual therapy sessions provided by physiotherapists and more limited patient education. Progress toward the individual functional goals identified should be addressed at follow up-visits and throughout treatment by other members of the health care team as well as the authorized physicians.

Documentation of this process should occur whenever diagnostic tests or referrals from the authorized treating physician are contemplated. The informed decision making process asks the patient to set their personal functional goals of treatment, describe their current health status and any concerns they have regarding adhering to the diagnostic or treatment plan proposed. The provider should clearly describe the following:

- The expected functional outcomes from the proposed treatment, or expected results and plan of action if diagnostic tests are involved
- Any side effects and risks to the patient
- Required post treatment rehabilitation time and impact on work, if any
- Alternative therapies or diagnostic testing

Before diagnostic tests or referrals for invasive treatment take place the patient should be able to clearly articulate the goals of the intervention, the general side effects and risks associated with it and their decision regarding compliance with the suggested plan. One study indicated that information provided only by video might not be sufficient education.

Practitioners must develop and implement an effective strategy and skills to educate patients, employers, insurance systems, policy makers, and the community as a whole. An education-based paradigm should always start with providing reassuring information to the patient and informed decision making. More in-depth education currently exists within a treatment regimen employing functional restoration, prevention, and cognitive behavioral techniques. Patient education and informed decision making should facilitate self-management of symptoms and prevention.

Personality/Psychological/Psychosocial Intervention

Psychosocial treatment is a well-established therapeutic and diagnostic intervention with selected use in acute pain problems and more widespread use in sub-acute and chronic pain populations. Psychosocial treatment is recommended as an important component in the total management of a patient with chronic low back pain and should be implemented as soon as the problem is identified.

If a diagnosis consistent with the standards of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (DSM) has been determined, the patient should be evaluated for the potential need for psychiatric medications. Use of any medication to treat a diagnosed condition may be ordered by the authorized treating physician or by the consulting psychiatrist. Visits for management of psychiatric medications are medical in nature and are not a component of psychosocial treatment. Therefore, separate visits for medication management may be necessary, depending on the patient and medications selected.

Psychosocial interventions include psychotherapeutic treatments for mental health conditions, as well as behavioral medicine treatments. These interventions may similarly be beneficial for patients without psychiatric conditions, but who may need to make major life changes in order to cope with pain or adjust to disability. Examples of these treatments include cognitive behavioral therapy (CBT), relaxation training, mindfulness training, and sleep hygiene training.

The screening or diagnostic workup should clarify and distinguish between pre-existing, aggravated, and/or purely causative psychological conditions. Therapeutic and diagnostic modalities include, but are not limited to, individual counseling and group therapy. Treatment can occur within an individualized model, a multi-disciplinary model, or a structured pain management program.

A psychologist with a PhD, PsyD, EdD credentials, or a psychiatric MD/DO may perform psychosocial treatments. Other licensed mental health providers or licensed health care providers with training in CBT, or certified as CBT therapists who have experience in treating chronic pain disorders in injured workers, may also perform treatment in consultation with a PhD, PsyD, EdD, or psychiatric MD/DO.

CBT refers to a group of psychological therapies that are sometimes referred to by more specific names, such as rational emotive behavior therapy, rational behavior therapy, rational living therapy, cognitive therapy, and dialectic behavior therapy. Variations of CBT methods can be used to treat a variety of conditions, including chronic pain, depression, anxiety, phobias, and post-traumatic stress disorder (PTSD). For patients with multiple diagnoses, more than 1 type of CBT might be needed. The CBT used in research studies is often "manualized CBT," meaning that the treatment follows a specific protocol in a manual. In clinical settings, CBT may involve the use of standardized materials, but it is also commonly adapted by a psychologist or psychiatrist to the patient's unique circumstances. If the CBT is being performed by a non-mental health professional, a manual approach would be strongly recommended. CBT must be distinguished from neuropsychological therapies used to teach compensatory strategies to brain injured patients, which are also called "cognitive therapy."

It should be noted that most clinical trials on CBT exclude subjects who have significant psychiatric diagnoses. Consequently, the selection of patients for CBT should include the following considerations. CBT is instructive and structured, using an educational model with homework to teach inductive rational thinking. Because of this educational model, a certain level of literacy is assumed for most CBT protocols. Patients who lack the cognitive and educational abilities required by a CBT protocol are unlikely to be successful. Further, given the highly structured nature of CBT, it is more effective when a patient's circumstances are relatively stable. For example, if a patient is about to be evicted, is actively suicidal, or is coming to sessions intoxicated, these matters will generally preempt CBT treatment for pain, and require other types of psychotherapeutic response. Conversely, literate patients whose circumstances are relatively stable, but who catastrophize or cope poorly with pain or disability are often good candidates for CBT for pain. Similarly, literate patients whose circumstances are relatively stable, but who exhibit unfounded medical phobias, are often good candidates for CBT for anxiety.

There is good evidence that cognitive intervention reduces low back disability in the short term and in the long term. In 1 of the studies the therapy consisted of six 2-hour sessions given weekly to workers who had been sick-listed for 8 to 12 weeks. Comparison groups included those who received routine care. There is good evidence that psychological interventions, especially CBT, are superior to no psychological intervention for chronic low back pain, and that self-regulatory interventions, such as biofeedback and relaxation training, may be equally effective. There is good evidence that 6 group therapy sessions lasting one and a half hours each focused on CBT skills improved function and alleviated pain in uncomplicated sub-acute and chronic low back pain patients. There is some evidence that CBT provided in seven 2-hour small group sessions can reduce the severity of insomnia in chronic pain patients. A Cochrane meta-analysis grouped very heterogeneous behavioral interventions and concluded that there was good evidence that CBT may reduce pain and disability but the effect size was uncertain. In total, the evidence clearly supports CBT, and it should be offered to all chronic pain patents who do not have other serious issues, as discussed above.

CBT is often combined with active therapy in an interdisciplinary program, whether formal or informal. It must be coordinated with a psychologist or psychiatrist. CBT can be done in a small group or individually, and the usual number of treatments varies between 8 and 16 sessions.

Before CBT is done, the patient must have a full psychological evaluation. The CBT program must be done under the supervision of a PhD, PsyD,

EdD, or psychiatric MD/DO.

Psychological DSM Axis I disorders are common in chronic pain. One study demonstrated that the majority of patients who had failed other therapy and participated in an active therapy program also suffered from major depression. However, in a program that included CBT and other psychological counseling, the success rate for return to work was similar for those with and without a DSM IV diagnosis. This study further strengthens the argument for having some psychological intervention included in all chronic pain treatment plans.

For all psychological/psychiatric interventions, an assessment and treatment plan with measurable behavioral goals, time frames, and specific interventions planned, must be provided to the treating physician prior to initiating treatment. A status report must be provided to the authorized treating physician every 2 weeks during initial more frequent treatment and monthly thereafter. The report should provide documentation of progress toward functional recovery and a discussion of the psychosocial issues affecting the patient's ability to participate in treatment. The report should also address pertinent issues such as pre-existing, aggravated, and/or causative issues, as well as realistic functional prognosis.

Refer to the original guideline document for time to produce effect, frequency, and optimum and maximum duration of psychological/psychiatric therapies.

Restriction of Activities

Continuation of normal daily activities is the recommendation for low back pain patients since immobility will negatively affect rehabilitation. Prolonged immobility results in a wide range of deleterious effects, such as a reduction in aerobic capacity and conditioning, loss of muscle strength and flexibility, increased segmental stiffness, promotion of bone demineralization, impaired disc nutrition, and the facilitation of the illness role.

Immobility may range from bed rest to the continued use of orthotics, such as lumbar support braces. While these interventions may occasionally have been ordered in the acute phase, the provider should be aware of their impact on the patient's ability to adequately comply with and successfully complete rehabilitation. There is strong evidence against the use of bed rest in acute low back pain cases without neurologic symptoms. Activity should be increased based on the improvement of core strengthening.

Patients should be educated regarding the detrimental effects of immobility versus the efficacious use of limited rest periods. Adequate rest allows the patient to comply with active treatment and benefit from the rehabilitation program. In addition, complete work cessation should be avoided, if possible, since it often further aggravates the pain presentation and promotes disability. Modified return to work is almost always more efficacious and rarely contraindicated in the vast majority of injured workers with low back pain.

Return to Work

Return to work and/or work-related activities whenever possible is one of the major components in low back pain management and rehabilitation. There is some evidence that an integrated care program including workplace interventions and graded activity teaching that pain need not limit activity is effective in returning patients with chronic low back pain to work, even with minimal reduction of pain. Return to work is a subject that should be addressed by each workers' compensation provider at the first meeting with the injured employee and updated at each additional visit. A return-to-work format should be part of a company’s health plan, knowing that return to work can decrease anxiety, reduce the possibility of depression, and reconnect the worker with society.

Because a prolonged period of time off work will decrease the likelihood of return to work, the first weeks of treatment are crucial in preventing and/or reversing chronicity and disability mindset. In complex cases, experienced nurse case managers may be required to assist in return to work. Other services, including psychological evaluation and/or treatment, jobsite analysis, and vocational assistance, may be employed.

Two counseling sessions with an occupational physician, and work site visit if necessary, may be helpful for workers who are concerned about returning to work. Another study found that low back pain claimants who received information on self-care and return to work had fewer episodes of relapse than those who did not receive the advice.

At least one study suggests that health status is worse for those who do not return to work than those who do. Self-employment and injury severity predict return to work. Difficulty with pain control, ADLs, and anxiety and depression were common.

The following should be considered when attempting to return an injured worker with chronic pain to work.

- Job history interview
- Coordination of care
- Communication
- Establishment of return-to-work status
- Establishment of activity level restrictions

- Rehabilitation and return to work
- Vocational assistance

Recommendations to Employers and Employees of Small Businesses

Employees of small businesses who are diagnosed with chronic pain may not be able to perform any jobs for which openings exist. Temporary employees may fill those slots while the employee functionally improves. Some small businesses hire other workers, and if the injured employee returns to the job, the supervisor/owner may have an extra employee. To avoid this, it is suggested that case managers be accessed through their payer or third-party administrator. Case managers may assist with resolution of these problems, as well as assist in finding modified job tasks, or find jobs with reduced hours, etc., depending on company philosophy and employee needs.

Recommendations to Employers and Employees of Mid-sized and Large Businesses

Employers are encouraged by the Division to identify modified work within the company that may be available to injured workers with chronic pain who are returning to work with temporary or permanent restrictions. To assist with temporary or permanent placement of the injured worker, it is suggested that a program be implemented that allows the case manager to access descriptions of all jobs within the organization.

Therapy–Active

The following active therapies are widely used and accepted methods of care for a variety of work-related injuries. A retrospective cohort study suggests that early referral to rehabilitation/physical therapy, within 14 days decreases the cost and likelihood of the need for later referrals and testing, thus decreasing overall medical costs. Active therapies are based on the philosophy that therapeutic exercise and/or activities are beneficial for restoring flexibility, strength, endurance, function, ROM, and alleviating discomfort. Active therapy requires an internal effort by the individual to complete a specific exercise or task. This form of therapy requires supervision from a licensed or registered occupational or physical therapist. The supervision may include verbal, visual, and/or tactile instruction(s). At times, the provider may help stabilize the patient or guide the movement pattern but the energy required to complete the task is predominantly executed by the patient.

Education and counseling should include 1) understanding of the strength inherent in the human spine, and stabilization musculature including the transversus abdominis and multifidus, 2) how neuroscience explains pain perception, 3) the favorable prognosis of low back pain, 4) use of active pain coping strategies that decrease fear and catastrophizing, 5) early resumption of normal activities while still experiencing pain, and 6) the importance of increasing activity levels. Patients should be instructed to continue active therapies at home as an extension of the treatment process in order to maintain improvement levels. Follow-up visits to reinforce and monitor progress and proper technique are recommended. Home exercise can include exercise with or without mechanical assistance or resistance and functional activities with assistive devices. The patient's baseline and progress should be measured using validated tools such as the Oswestry Disability Index or the Roland–Morris Disability Questionnaire or following objective functional measurements.

Therapists should notify the authorized treating physician when 1) clinical findings suggest serious medical or psychological pathology, 2) reported activity limitations are not consistent with the diagnosis, or 3) symptoms are not improving subjectively or objectively after 4 weeks or resolving with interventions focused on normalizing body function. Various means can be used to measure the functional success of treatment; however, it appears that an increase of 5 kg lifting or 7 points on the pain disability index may be useful.

On occasion, specific diagnoses and post-surgical conditions may warrant durations of treatment beyond those listed as "maximum." Factors such as exacerbation of symptoms, re-injury, interrupted continuity of care and co-morbidities may also extend durations of care. Specific goals with objectively measured functional improvement during treatment must be cited to justify extended durations of care. It is recommended that, if no functional gain is observed after the number of treatments under "time to produce effect" have been completed, then alternative treatment interventions, further diagnostic studies, or further consultations should be pursued.

The following active therapies are listed in alphabetical order. Refer to the original guideline document additional information on each, including time to produce effect, frequency, and optimum and maximum duration of treatments.

- Activities of daily living (ADLs)
- Aquatic therapy
- Back schools
- Functional activities
- Functional electrical stimulation
- Neuromuscular re-education
- Therapeutic exercise
- Work conditioning

- Work simulation

Therapy–Passive

Most of the following passive therapies and modalities are generally accepted methods of care for a variety of work-related injuries. Passive therapy includes those treatment modalities that do not require energy expenditure on the part of the patient. They are principally effective during the early phases of treatment and are directed at controlling symptoms such as pain, inflammation, and swelling and to improve the rate of healing soft tissue injuries. They should be used adjunctively with active therapies, such as postural stabilization and exercise programs to help control swelling, pain, and inflammation during the active rehabilitation process (refer to Section F.12., "Therapy–Active," in the original guideline document). Passive therapies may be used intermittently as a therapist deems appropriate or regularly if there are specific goals with objectively measured functional improvements during treatment.

The following passive therapies and modalities are listed in alphabetical order. Refer to the original guideline document for additional information, including indications for each therapy, time to produce effect, frequency, and optimum and maximum duration of treatments.

- Electrical stimulation (unattended)
- Iontophoresis (not recommended)
- Low level laser (not recommended)
- Manipulation
- Manipulation under general anesthesia (MUA) (not recommended)
- Manipulation under Joint anesthesia (MUJA) (not recommended)
- Massage – Manual or mechanical
- Mobilization (joint)
- Mobilization (soft tissue)
- Short-wave diathermy
- Superficial heat and cold therapy (excluding infrared therapy)
- Traction – Manual
- Traction – Mechanical (not recommended)
- Transcutaneous electrical nerve stimulation (TENS)
- Ultrasound (including phonophoresis) (not recommended)
- Vertebral axial decompression (VAX-D)/DRX, 9000

Vocational Rehabilitation

This is a generally accepted intervention, but Colorado limits its use as a result of Senate Bill 87-79. Initiation of vocational rehabilitation requires adequate evaluation of patients for quantification of highest functional level, motivation, and achievement of MMI. Vocational rehabilitation may be as simple as returning to the original job or as complicated as being retrained for a new occupation.

It may also be beneficial for full vocational rehabilitation to be started before MMI if it is evident that the injured worker will be unable to return to his/her previous occupation. A positive goal and direction may aid the patient in decreasing stress and depression and promote optimum rehabilitation.

Therapeutic Procedures–Operative

In order to justify operative interventions, clinical findings, clinical course, and diagnostic tests must all be consistent resulting in a reasonable likelihood of at least a measurable and meaningful functional and symptomatic improvement. A comprehensive assimilation of these factors must lead to a specific diagnosis with positive identification of pathologic conditions and in most cases a specific site of nerve root compression, spinal cord compression, or spinal instability. It is imperative to rule out non-physiologic modifiers of pain presentation or non-operative conditions mimicking radiculopathy or instability (e.g., psychological conditions, peripheral neuropathy, myofascial pain, rheumatologic, or other pain syndromes, etc.) prior to consideration of elective surgical intervention.

Operative treatment is indicated when the natural history of surgically treated lesions is better than the natural history for non-operatively treated lesions. All patients being considered for surgical intervention should first undergo a comprehensive neuro-musculoskeletal examination to identify mechanical pain generators that may respond to non-surgical techniques or may be refractory to surgical intervention. Patients who demonstrate centralization on directional preference testing may not need surgery when treated with directional preference neuromuscular educations (refer to Section F.12.f., "Therapeutic Exercise," in the original guideline document).

While sufficient time allowances for non-operative treatment are required to determine the natural cause and response to non-operative treatment

of lumbar pain disorders, an accurate diagnosis and timely decision making for operative intervention are critical. Thorough neurologic exams should be performed periodically to assure timely treatment; to avoid de-conditioning and increased disability; and to treat emergent pathology or neurologically compromising conditions which may require early surgery.

Brief psychological screening tools, or more frequently full evaluations, are done to predict surgical success. Psychological screening is indicated for all patients with continuing pain who are considering surgical interventions as indicated under the specific surgical procedure. Lower patient satisfaction after repeat surgical procedures and other treatment are related to pre-existing depression.

In general, if the program of non-operative treatment fails, operative treatment is indicated when symptoms and findings suggest a surgically amenable problem and:

- Improvement of the symptoms has plateaued and the residual symptoms of pain and functional disability are unacceptable at the end of 6 to 12 weeks of active therapy and manual treatment (mere passage of time with poorly guided treatment is not considered an active treatment program). In cases of myelopathy and some cases of severe nerve root compression, earlier intervention is indicated; or
- Frequent recurrences of symptoms cause serious functional limitations, even if a non-operative active treatment program provides significant improvement of symptoms, and restoration of function on each recurrence; and
- The patient and treating physician have identified functional operative goals and the likelihood of achieving improved ability to perform activities of daily living or work activities. The patient should agree to comply with the pre- and post-operative treatment plan including home exercise. The provider should be especially careful to make sure the patient understands the amount of post-operative treatment required and the length of partial- and full-disability expected post-operatively. The patient should have committed to the recommended post-operative treatment plan and fully completed the recommended active, manual and pre-operative treatment plans.

There are some clinical scenarios which necessitate surgical interventions. Surgical workup and implementation of decompression of patients with herniated nucleus pulposus and radiculopathy should occur within six to twelve weeks, at the latest, after injury within the above stated contingencies. Small herniations and most protrusions are often not pain generators, however small foraminal disc herniations are likely to compress the nerve root and may require surgical removal.

In order to qualify for surgery for nerve root compression, the patient should exhibit the following signs of radiculopathy before invasive procedures are considered:

i. Pain in the legs greater than in the low back which interferes with function, return to work and/or active therapy; and
ii. Physical exam findings of abnormal reflexes, motor weakness or radicular sensation deficits; and
iii. Findings on the MRI which indicate impingement of nerves or the spinal cord corresponding to reproducible physical exam findings.

Treatment of myelopathy may occur earlier. Surgical procedures should be directed toward neurological findings which correlate with MR imaging. For the unusual patients with refractory lumbar pain in whom fusion is being considered, it is strongly recommended that a decisive commitment to surgical or non-surgical interventions occur within five months following injury.

Re-operation is indicated only when the functional outcome following the re-operation is expected to be better, within a reasonable degree of certainty, than the outcome of other non-invasive or less invasive treatment procedures. "Functional outcomes" refer to the patient's ability to improve functional tolerances such as, standing, walking, strength, endurance, functional lumbar range of motion, and/or vocational status. While timely surgical decision-making is critical to avoid de-conditioning and increased disability, a time limited trial of reconditioning should be tried prior to re-operation. Re-operation has a high rate of complications and failure and may lead to disproportionately increased disability.

Every post-operative patient should be involved in an active treatment program after clearance by the surgeon (refer to Section F.12., "Therapy–Active," in the original guideline document). Interdisciplinary interventions should be strongly considered post-operatively in any patient not making functional progress within expected time frames (refer to Section F.5., "Interdisciplinary Rehabilitation Programs," in the original guideline document).

Informed decision making should be documented for all invasive procedures. This must include a thorough discussion of the pros and cons of the procedure and the possible complications as well as the natural history of the identified diagnosis. Since most patients with the most common conditions will improve significantly over time, without invasive interventions, patients must be able to make well-informed decisions regarding their treatment.

Return to work restrictions should be specific according to the recommendations in Section F.11., "Return to Work," in the original guideline document. Most surgical patients can return to a limited level of duty between three to six weeks. Full activity is generally achieved between three months to one year, depending on the procedure, the type of duties performed, and healing of the individual. Patient should be informed of expected time off work.

Discectomy (Usually Accompanied by Partial Laminectomy)

Description

To enter into and partially remove the disc. May be an open procedure or minimally invasive, and usually involves partial laminectomy.

Complications

Include, but are not limited to, nerve damage, spinal fluid leakage, infection, and hemorrhage.

Surgical Indications

To include all of the following: specific diagnosis of nerve root compression proven by MRI or CT myelogram and correlated to exam findings, primary radicular symptoms, radiculopathy on exam (refer to beginning of this section for a description of radiculopathy) and failure of 6 weeks of active therapy. In some cases, surgery may need to occur sooner due to an individual's inability to participate in active therapy. Epidural injections have not been proven to have long-term benefit; however they may be trialed prior to surgery if the patient wishes to try to avoid surgery or is unable to participate in therapy after the first 2 weeks.

There is good evidence that after 6 weeks of active therapy, those patients with persistent radicular leg pain and an image-confirmed disc herniation have better functional outcomes than non-operated patients. This outcome is more likely to be observed within the first 2-3 months after surgery. However non-operative groups also improved significantly over 2 years.

The purpose of spinal injections, as well as surgery, is to facilitate active therapy by providing short-term relief through reduction of pain. Since most patients with these conditions will improve significantly over time, without invasive interventions, patients must be able to make well-informed decisions regarding their treatment.

Refer to the original guideline document for information on operative and post-operative treatment.

Percutaneous Discectomy

Description

An invasive operative procedure to accomplish partial removal of the disc through a needle which allows aspiration of a portion of the disc trocar under imaging control.

Complications

Include, but are not limited to, injuries to the nerve or vessel, infection, hematoma, and incomplete nerve root decompression.

Surgical Indications

Percutaneous discectomy is indicated only in cases of suspected septic discitis in order to obtain diagnostic tissue. The procedure is not recommended for contained disc herniations or bulges with associated radiculopathy due to lack of evidence to support long-term improvement.

Laminotomy/Laminectomy/Foramenotomy/Facetectomy for Central or Lateral Spinal Stenosis

Description

These procedures provide access to produce neural decompression by partial or total removal of various parts of spinous elements.

Complications

Include, but are not limited to, nerve injury, post-surgical instability, CSF leakage, hematoma, infection, and incomplete decompression.

Surgical Indications

Include all of the following:

- Radicular symptoms or symptoms of neurogenic claudication, often with clinical evidence of radiculopathy that correlates with the patient's pain and findings
- Evidence of nerve root compression generally proven by MRI or CT myelogram
- Failure of non-surgical care. For patients with stenosis non-surgical active treatment should generally consist of 6 to 12 weeks for an adequate trial. Patients with severe stenosis that correlates with symptoms often do not improve with conservative care.

Refer to the original guideline document for information on operative and postoperative treatment.

Spinal Fusion (Usually Combined with Decompression)

Description

Use of bone grafts, sometimes combined with instrumentation, to produce a rigid connection between two or more adjacent vertebrae.

Complications

Complications include instrumentation failure, bone graft donor, site pain, superficial infection, deep wound infection, and graft extrusion. There is an increased likelihood of complications with instrumented fusion, although the majority of them are minor. There is some evidence that morbid obesity increases hospital length of stay, mortality and postoperative complications of spinal fusion surgery and results in concomitant increases in cost. Fusion can accelerate adjacent level disease. In one study, more than one-third of patients required surgery at an adjacent level by 10 years. Refer to the following recombinant human bone morphogenetic protein section in the original guideline document for complications from their use.

Surgical Indications

A timely decision-making process is recommended when considering patients for possible fusion. The treatment for some patients with lumbar fractures may be immediate fusion. For chronic low back problems, fusion should not be performed within the first five months of symptoms, except for fracture, dislocation, or for some patients with functional loss due to stenosis and instability.

Refer to the original guideline document for additional information on surgical indications as wells as the following topics:

- Use of recombinant human bone morphogenetic protein (rhBMP-2) in fusions
- Diagnostic indications for spinal fusion
- Pre-operative surgical indication for spinal fusion
- Operative treatment
- Post-operative treatment
- Return to work following spinal fusion

Dynamic Neutralization System

A possible option to spinal fusion for patients with grade 1 instability and symptomatic stenosis is a currently available in a posterior stabilization system device. This device attaches with pedicle screws and intends to address instability while allowing some segmental motion. It is expected to protect adjacent disc levels from the deterioration experienced with a complete fusion. It is also thought to provide a less invasive, less risky surgical procedure for patients with degenerative disc disease and functionally impairing pain with instability and stenosis. The U.S. Food and Drug Administration (FDA) has not fully approved this system for this indication. Some case series of patients with stenosis and grade 1 instability have indicated less operating time, more rapid return to function and a slightly better outcome than those who received decompression and fusion. At this time the procedure is not recommended. Further studies may provide more conclusive information. If it is being considered the patient should not have osteoporosis and must meet all of the indications for fusion at one or two levels, including prior authorization. They should also have predominant leg pain over back pain.

SI Joint Fusion

Description

Use of bone grafts, sometimes combined with instrumentation.

Complications

Instrumentation failure, bone graft donor site pain, in-hospital mortality, deep infection, superficial infection, and graft extrusion.

Surgical Indications

SI joint fusion may be indicated for stabilization of a traumatic severe disruption of the pelvic ring. This procedure has limited use in minor trauma and would be considered only on an individual case-by-case basis. In patients with typical mechanical low back pain, this procedure is considered to be investigational. Until the efficacy of this procedure for mechanical low back pain is determined by an independent valid prospective outcome study, this procedure is not recommended for mechanical low back pain.

Implantable Spinal Cord Stimulators

Reserved for those low back pain patients with pain, radiculopathy, and failed surgery of greater than six months duration who have not responded to the standard non-operative or operative interventions previously discussed within this document. Refer to the NGC summary of the Colorado Division of Workers' Compensation Chronic pain disorder medical treatment guidelines.

Intradiscal Electrothermal Annuloplasty (IDEA) (More Commonly Called IDET, or Intradiscal Electrothermal Therapy)

IDET is an outpatient procedure. A wire is guided into the identified painful disc using fluoroscopy. The wire is then heated at the nuclear annular junction within the disc. Due to lack of evidence indicating benefit from this procedure, it is not recommended.

Interspinal Spacers

Description

Multiple interspinous spacer devices (IFDs) have been utilized to treat older patients (age 50 and over) with lumbar spinal stenosis (LSS) and intermittent neurogenic claudication (INC). Interspinous process decompression theoretically relieves narrowing of the spinal canal and neural foramen in extension, thereby reducing the symptoms of INC, secondary to LSS.

Complications

Complications include, but are not limited to, symptomatic spinous process fractures, new radicular defects, recurrent back pain, device extrusion, device failure with need for further surgery, and bilateral foot drop.

Surgical Indications

The device is indicated for treatment of patients 50 or older suffering from neurogenic intermittent claudication caused by lumbar spinal stenosis (with X-ray, MRI and/or CT evidence of thickened flavum, narrowed lateral recess and/or central canal narrowing).

Refer to the original guideline document for more information on indications, contraindications, operative treatment, post-procedure therapy, and return to work after interspinal spacers placement.

Laser Discectomy

Involves the delivery of laser energy into the center of the nucleus pulposus using a fluoroscopically guided laser fiber under local anesthesia. The energy denatures protein in the nucleus, causing a structural change, which is intended to reduce intradiscal pressure. Its effectiveness has not been shown. Laser discectomy is not recommended.

Artificial Lumbar Disc Replacement

Description

This involves the insertion of a prosthetic device into an intervertebral space from which a degenerated disc has been removed, sparing only the peripheral annulus. The endplates are positioned under intraoperative fluoroscopic guidance for optimal placement in the sagittal and frontal planes. The prosthetic device is designed to distribute the mechanical load of the vertebrae in a physiologic manner and maintain ROM.

General selection criteria for lumbar disc replacement includes symptomatic one-level degenerative disc disease. The patient must also meet fusion surgery criteria, and if the patient is not a candidate for fusion, a disc replacement procedure should not be considered. Additionally, the patient should be able to comply with pre-and post-surgery protocol.

Refer to the original guideline document for additional information on artificial lumbar disc replacement including complications, surgical indications, contraindications, and post-operative treatment.

Kyphoplasty

Description

A surgical procedure for the treatment of symptomatic thoracic or lumbar vertebral compression fractures, most commonly due to osteoporosis or other metabolic bone disease, and occasionally with post-traumatic compression fractures and minor burst fractures that do not significantly compromise the posterior cortex of the vertebral body. Pain relief can be expected in approximately 90% of patients. There is good evidence that kyphoplasty provides rapid improvement in function in the initial months after the fracture as compared to non-operative treatment or analgesics alone. There is no clear long-term advantage. The natural history of recovery from vertebral fractures would indicate that most patients will recovery in approximately 12 weeks. There is no evidence that kyphoplasty is superior to vertebroplasty.

Refer to the original guideline document for additional information on complications, operative treatment, surgical indications, and contraindications.

Vertebroplasty

Description

Vertebroplasty is a minimally invasive surgical procedure for the treatment of painful thoracolumbar vertebral compression fractures secondary to osteoporosis or other metabolic bone disease. Traditionally a low-viscosity acrylic bone cement, polymethylmethacrylate (PMMA), is injected with high pressure into the vertebral body under fluoroscopic guidance. Other types of bone cement such as high-viscosity PMMA, glass polymers, hydroxyapatite, and calcium phosphate have recently been made commercially available. The procedure is usually performed under intravenous sedation or light general anesthesia. A bone biopsy needle or trocar needle (11- to 13-gauge) is placed into the vertebral body and cement is injected very slowly under constant fluoroscopic guidance to minimize cement leakage. The goal of the procedure is to stabilize the spine and to relieve pain.

Refer to the original guideline document for additional information on vertebroplasty including complications, indications, and contraindications.

Percutaneous RF Disc Compression

An investigational procedure that introduces a 17-gauge cannula under local anesthesia and fluoroscopic guidance into the nucleus pulposus of the contained herniated disc, using RF energy to dissolve and remove disc material. Pressure inside the disc is lowered as a result. There have been no randomized clinical trials of this procedure at this time. Percutaneous RF disc decompression is not recommended.

Nucleus Pulposus Replacement

Involves the introduction of a prosthetic implant into the intervertebral disc, replacing the nucleus while preserving the annulus fibrosus. It is limited to investigational use in the United States at this time. It is not recommended.

Epiduroscopy and Epidural Lysis of Adhesion

Refer to Section F.4., "Injections–Other (Including Radiofrequency)," in the original guideline document.

Intraoperative Monitoring

A common intraoperative electrodiagnostic technique that may include somatosensory evoked potentials (SSEP), motor evoked potentials (MEP), or pedicle screw monitoring. The monitoring procedure is frequently used to evaluate spinal cord integrity and screw placement during the operative procedure. For details regarding training and technical procedures refer to Rule 18.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Low back pain

Guideline Category

Counseling

Management

Rehabilitation

Treatment

Clinical Specialty

Chiropractic

Emergency Medicine

Family Practice

Internal Medicine

Neurological Surgery

Physical Medicine and Rehabilitation

Psychiatry

Psychology

Radiology

Surgery

Intended Users

Advanced Practice Nurses

Chiropractors

Health Care Providers

Health Plans

Hospitals

Managed Care Organizations

Nurses

Occupational Therapists

Patients

Pharmacists

Physical Therapists

Physician Assistants

Physicians

Psychologists/Non-physician Behavioral Health Clinicians

Public Health Departments

Social Workers

Utilization Management

Guideline Objective(s)

To provide advisory and educational guidelines for the treatment of low back pain that are enforceable under the Colorado Workers' Compensation Rules of Procedure

Target Population

Individuals who qualify as injured workers with low back pain under Colorado's Workers' Compensation Act

Interventions and Practices Considered

Non-operative Therapeutic Procedures*

1. Acupuncture
2. Biofeedback
3. Therapeutic injections
    - Epidural steroid injections (ESI)
    - Intradiscal steroid injections
    - Sacroiliac (SI) joint injection
    - Transforaminal injection with etanercept
    - Zygapophyseal (facet) injections
    - Botulinum toxin injections
    - Epiduroscopy and epidural lysis of adhesions
    - Prolotherapy
    - Radiofrequency (RF) ablation - dorsal nerve root ablation
    - RF denervation – medial branch neurotomy/facet rhizotomy
    - RF denervation – SI joint cooled
    - Transdiscal biacuplasty
    - Trigger point injections and dry needling treatment
4. Interdisciplinary rehabilitation programs (formal and informal)
5. Medications
    - Acetaminophen
    - Antibiotics for chronic pain secondary to disc herniation
    - Intravenous steroids
    - Glucosamine
    - Muscle relaxants
    - Non-steroidal anti-inflammatory drugs (NSAIDs)
    - Opioids
    - Oral steroids
    - Psychotropic/anti-anxiety/hypnotic agents
    - Tramadol
6. Orthotics
    - Foot orthoses and inserts
    - Lumbar support devices
    - Lumbar corsets and back belts
    - Lumbosacral bracing
7. Patient education
8. Personality/psychological/psychosocial/psychiatric interventions (including cognitive behavioral therapy [CBT])
9. Restriction of activities
10. Return to work
    - Job history interview
    - Coordination of care
    - Communication
    - Establishment of a return-to-work status
    - Establishment of activity level restrictions
    - Rehabilitation and return to work
    - Vocational assistance
11. Active therapy
    - Activities of daily living (ADLs)

    - Aquatic therapy
    - Back schools
    - Functional activities
    - Functional electrical stimulation
    - Neuromuscular re-education
    - Therapeutic exercise
    - Work conditioning
    - Work simulation
12. Passive therapy
    - Electrical stimulation (unattended)
    - Iontophoresis
    - Low level laser
    - Manipulation
    - Manipulation under general anesthesia (MUA)
    - Manipulation under joint anesthesia (MUJA)
    - Manual or mechanical massage
    - Joint or soft tissue mobilization
    - Short-wave diathermy
    - Superficial heat and cold therapy (including infrared therapy)
    - Manual or mechanical traction
    - Transcutaneous electrical nerve stimulation (TENS)
    - Ultrasound (including phonophoresis)
    - Vertebral axial decompression (VAX-D)/DRX, 9000
13. Vocational rehabilitation

Operative Therapeutic Procedures*

1. Discectomy (usually accompanied by laminectomy)
2. Percutaneous discectomy
3. Laminotomy/laminectomy/foramenotomy/facetectomy for central or lateral spinal stenosis
4. Spinal fusion (usually combined with decompression)
5. Dynamic neutralization system
6. SI joint fusion
7. Implantable spinal cord stimulators
8. Intradiscal electrothermal annuloplasty (IDEA) (more commonly called IDET, or intradiscal electrothermal therapy)
9. Interspinal spacers
10. Laser discectomy
11. Artificial lumbar disc replacement
12. Kyphoplasty
13. Vertebroplasty
14. Percutaneous RF disc decompression
15. Nucleus pulposus replacement
16. Epiduroscopy and epidural lysis of adhesions
17. Intraoperative monitoring

*Note: See the "Major Recommendations" field and the original guideline document. Not all of the listed interventions and practices are recommended routinely or generally.

Major Outcomes Considered

- Functional improvement (time to return to work, ability to return to original job, etc.)
- Change in pain scores (Visual Analog Scale [VAS], Oswestry Disability score, etc.)
- Duration of therapeutic effect
- Side effects or complications
- Response rate

- Surgical success rate
- Time on disability

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

General Literature Search Strategy for Medical Treatment Guidelines

Studies were identified through the electronic database of PubMed (with specified search topics), and related links from articles identified by searches. For some articles, Web of Science, a literature citation database, was used when it was desirable to find literature that cited a particular article. Relevant evidence statements from Cochrane and *British Medical Journal* (BMJ) Clinical Evidence were reviewed. Selected guidelines/systematic reviews were also reviewed. The reference lists from other literature and tables of content from related journals were scanned for relevant articles. Suggestions from various volunteer advisory bodies to the Division of Workers' Compensation were solicited.

Literature reviewed was in English. Literature searches were limited according to study type and human adults. Only randomized clinical trials (RCT) or meta-analyses were used for evidence statements regarding treatment. RCTs that compared an intervention (for example, surgery) with not using that intervention (for example, non-operative treatment) were designated as more relevant to workers' compensation guidelines than those RCTs which compared variations on technique or types of devices.

Beginning with the Traumatic Brain Injury Medical Treatment Guidelines Revision of 2012, if meta-analyses were of high enough quality, then previous RCTs that were incorporated into the selected meta-analyses may not have been individually critiqued. Selected RCTs published after Cochrane meta-analyses were evaluated as to whether they would have likely met the Cochrane inclusion criteria. If so, the Cochrane software (RevMan) was used to update the pooled effect measure and compare it with the original Cochrane report. Diagnostic accuracy studies were critiqued for diagnostic testing evidence and cohort, cross-sectional and case-control studies were critiqued for causation evidence statements. Literature which did not meet requirements for evidence statements could be referenced if it furnished useful background information or described interventions which are considered generally accepted by a consensus of health care providers. This information sometimes contributed to consensus decisions by the multidisciplinary task force drafting the guidelines. Literature that was determined either be unrelated to the clinical issue, did not reflect interventions likely to occur in Colorado, or which had such poor quality on initial review that it could not qualify for evidence nor provide meaningful input was not critiqued. All articles sent by the public were formally reviewed.

Specific Search Strategy

All searches were done on PubMed. The literature search included articles published from 2006 to 2012. In a number of instances, the search years were "unrestricted" so that Division staff could more comprehensively analyze an intervention. The search was conducted between July 2012 and January 2013.

Search terms included: lumbar disc arthroplasty; acute low back pain and acupuncture; balneotherapy; centralization; cognitive behavioral therapy, back pain, and neck pain; combined modality therapy, low back pain; directional preference; epidural steroid injection, back pain; ergonomics programs; facet joint block, low back pain; functional electrical stim; infrared therapy; interferential therapy; kyphoplasty; low level laser therapy, low back pain; lumbar discography, low back pain; lumbar Spine fusion; massage and low back pain; McKenzie assessment; microdiscectomy; phonophoresis; plasma disc decompression; selective nerve root block, low back pain; shortwave diathermy; SI joint block, low back pain; SI joint surgery; smoking cessation and low back pain; TENS; traction; ultrasound therapy; VAX-D; vertebroplasty.

Number of Source Documents

A total of 409 articles were initially identified.

Abstracts were reviewed and articles were then excluded based on the criteria below:

- Lack of relevancy to workers' compensation non-chronic back pain population
- Major obvious errors in study protocol (e.g., lack of control group even though study was listed as a randomized controlled trial [RCT])
- Whether they were included in another meta-analysis (e.g., Cochrane Collaboration, *British Medical Journal* [BMJ] Clinical Evidence)
- Duplicates
- Study too old
- Cadaverous studies
- Pediatric population
- Preliminary results
- Healthy volunteers
- Studies not applicable to treatment guidelines spine conditions, such as tumor studies.
- Studies too technical in nature to meet the objective of the guideline (examples, types of screws used in surgery)

This revealed 103 studies for further review.

Methods Used to Assess the Quality and Strength of the Evidence

Subjective Review

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Grading of Systematic Reviews and Meta-Analyses

Criterion	Green	Yellow	Red	Comments
The study is in fact identified as a systematic review or meta-analysis	"Systematic review," "meta-analysis," or both, are in the title of the article, and the abstract supports the design in the title	The title is ambiguous, but the abstract shows that the authors did a systematic review	The article is a narrative review or an overview, or is done by a single author	"Systematic review" and "meta-analysis" are generally recognized terms for a specific type of original research; narrative reviews are subject to biases which systematic reviews and meta-analyses methodically control for
Objectives of the systematic review or meta-analysis	Clearly stated in terms of PICOS: Patient population (disease, age, setting), Intervention (dose, frequency, etc.), Comparator (control group interventions), Outcome (morbidity, mortality, symptoms, function), and Study design (randomized trials only, broader design criteria)	PICOS elements all reported, but some ambiguity in some elements (e.g., Comparator described as "standard care" or "usual care" without further description)	One or more PICOS element missing or uninterpretable	The question being addressed should be clear from the abstract; it may be narrow or broad, but the scope and potential applicability should be well defined
Characteristics of eligible studies	In addition to PICOS, study characteristics defined in terms of restrictions for inclusion (e.g., minimum length of follow-up, whether co-interventions are included), and scope of reports (language, years of publication, unpublished	Ambiguity exists for some of the characteristics of eligible studies	Eligibility of studies is unclear, and scope of reports is not specified	

Criterion	Green	Yellow	Red	Comments
Information sources	Multiple information sources are clearly specified: databases (PubMed, Ovid, EMBASE, Cochrane, Web of Science), hand searches of tables of contents of relevant journals, meeting abstracts, reference lists, contacts with authors, manufacturers, trial registries)	Search limited to published material from two or more sources, without additional searching of registries or contact with authors	Search limited to a single information source (e.g., PubMed only)	While PubMed is a large and nearly comprehensive database, its yield can be influenced by how articles are indexed by the National Library of Medicine; additional sources of information can materially affect the conclusions of a systematic review or meta-analysis
Search strategy	Full electronic search strategy for at least one major database, with dates (e.g., PubMed 1970-October 2009), limits, combinations of search terms, such that it can be replicated by the reader	Databases and search terms are given, but there is some ambiguity in the strategy (e.g., PubMed "through 2007"), and replication by the reader would be difficult	Databases and search terms are too broad and vague to permit replication by the reader	Often given in an appendix to the article or in an online supplement, the strategy should be readily accessible
Study selection	Specification of which criteria determine eligibility for inclusion (e.g., randomization to specified interventions, which outcomes were required to be reported) and for quality (e.g., allocation concealment, intention-to-treat analysis, blinding) with at least two reviewers identified by initials; inter-rater agreement and methods of resolving disagreement are specified; a flow diagram enumerates articles retrieved from search, articles excluded after screening, and articles included for meta-analysis	Two or more reviewers screen articles for inclusion, but there is some ambiguity in the criteria for inclusion or for inter-rater agreement and methods of resolving disagreement; flow diagram is lacking	Only one reviewer selects studies; criteria are vague	Quality assessment should focus on risk of bias; scoring of articles for quality is not necessary and may be misleading. There is no standard process for selecting studies, but the process used by the reviewers should be clear enough to allow the reader to determine which studies might meet the test of inclusion
Outcomes for analysis	Meta-analysis is restricted to pre-specified primary and secondary outcomes, and exploratory (hypothesis-generating) analyses in the source literature are excluded from meta-analysis	Meta-analysis combines pre-specified primary and secondary outcomes in the source literature with exploratory analyses in the same literature, but assigns exploratory analyses a lower weight	Meta-analysis treats exploratory analyses in source literature on an equal basis with the pre-specified primary and secondary analyses	Exploratory analyses are too likely to be reported when they arise from the play of chance, and should not be included in any meta-analysis of the same outcomes; their inclusion is likely to bias the meta-analysis
Summary measures for meta-analysis with or without	Principal summary measures (relative risk, risk difference, odds ratio, difference in means, hazard ratio) are specified and appropriate to the outcome measure; if NNT are reported, there is a fixed event rate in the control groups	Risk ratios or odds ratios are reported, and NNT is not reported if there is a difference in the	Risk ratios or odds ratios are reported, but NNT is reported even when there	Relative risks and odds ratios are generally more stable for summary measures than risk differences; pooled NNT is misleading if the control

Criterion	Green	Yellow	Red	Comments
pooled Number Needed to Treat (NNT)	for the studies being combined	control group event rates across the different studies	is a difference in control group event rates across the different studies (the underlying baseline risks are not equal)	group event rate (the baseline risk) is different across studies, even if the risk ratio is the same
Meta-analysis presentation	Results of meta-analysis are presented as an estimated summary effect (with confidence interval) across all included studies, displaying a forest plot with weights and confidence intervals for the included studies; a measure of heterogeneity is presented (e.g., I^2); the choice of fixed effect or random effects model is explained, and, if there is significant heterogeneity, there is an attempt to examine possible sources of heterogeneity	Estimated summary effect with confidence interval, with an estimate of heterogeneity, and an explanation of the choice of fixed or random effects model; however, an examination of sources of heterogeneity is lacking	Summary effect measure with confidence interval, but heterogeneity measures and examinations are lacking	No hard and fast rule dictates the choice of model, but because a fixed effect model assumes a single common effect size across studies, there should be a discussion of why it is appropriate for the included studies

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Criteria for evidence are drawn principally from the Cochrane Risk of Bias tool for individual randomized trials and from the PRISMA statement for systematic reviews. Nonrandomized trials may sometimes be upgraded to evidence statements when all Grading of Recommendations Assessment, Development and Evaluation (GRADE) criteria are met.

The strength and limitations of the body of evidence are clearly identified. Division of Workers' Compensation Assessment Criteria on Systematic Reviews and Meta-analyses list assessment criteria for strengths and limitations of selected bodies of literature (see the "Rating Scheme for the Strength of the Evidence" field). Also, areas that do not have evidence and thus are consensus-based are delineated in the guidelines.

The evidence table contains summaries of the critiques that were completed for individual scholarly articles used in the Cervical Spine Medical Treatment Guidelines. Scholarly articles are given an assessment of "adequate," "inadequate," or "high quality." When Division of Workers' Compensation staff completed additional statistical pooling, this is noted in the "Division Staff Assessment Column using RevMan (Cochrane Collaboration of Systematic Reviews). These are denoted with a **. In multiple cases, literature from the Cochrane Collaboration was reviewed.

It should be noted that one scholarly article may be graded at different levels for different interventions. For those deemed inadequate, a brief rationale is provided. The criteria for the aforementioned assessment designations are located on the Division of Workers' Compensation Website .

The articles that are graded as either adequate or high quality are then translated into "some evidence," "good evidence," and "strong evidence" as defined in the General Guidelines Principles, located in each of the Division Medical Treatment Guidelines (see the "Rating Scheme for the Strength of the Recommendations" field).

Because the guideline developers synthesize the medical evidence as much as possible, one assessment (or group of assessments) may potentially create more than one evidence statement. It is also possible that two assessments may be combined (e.g., two "adequates" to create a higher level

of evidence (for example, elevating a statement from "some" to "good" evidence). It should also be noted that some scholarly literature that focuses on the lumbar spine may also be clinically applicable to care of the injured worker with disorders of the cervical spine.

The evidence table is a summary and is based on critiques of scholarly articles. The full critiques are publicly available on the Division of Workers' Compensation Website (see the "Availability of Companions Documents" field).

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Evidence statements are formatted. General clinical reviews are collected and used to make suggested recommendations for consensus consideration. The Task Force reaches consensus by vote (unanimous decision in most cases). The health benefits, side effects and risks are considered in formulating the recommendations. These are fully described for groups and considered by the Task Force. There is an explicit link between recommendations and supporting evidence (presented in the referenced version of the guideline on the Department of Workers' Compensations website, wherein each evidence statement is accompanied by author and year of the bibliography/critiqued article).

Guidelines Updating Process

The State of Colorado Division of Workers' Compensation Medical Treatment Guidelines updating process is completed in several stages. Initially, current medical literature related to the guideline is systematically reviewed, critiqued, and graded by the Division and the multi-disciplinary Task Force. Next, appropriate medical evidence and consensus are incorporated concurrently into the Guideline, section by section. During this stage, Task Force members will be appointed for projects, working in sub-groups or individually, according to the task.

Guideline updating processes and resources dedicated to supporting the Task Force includes:

- Medical literature review and grading, with the assistance of a professional Research Methodologist
- Evidence and consensus parameters to assist in the revision and evaluation of treatment recommendations
- A multi-disciplinary Advisory Panel and other advisory bodies to provide clinical feedback to the Task Force and the Division
- Administrative support and coordination, allowing participants to focus on clinical issues
- Opportunities for members to provide feedback on ways to improve the update process

Selection of Task Force Members

Health care disciplines required to participate in the task force process are identified. Individuals selected should be Level I or II Accredited Providers (if applicable), Board Certified in their area of specialty, in good standing within their medical specialty organization, and specialize in treatment of injured workers. Task force membership also includes non-physician members of the workers' compensation system, such as: therapists, psychologists, attorneys, and risk managers. Prior task force participation is not necessary.

Grading Recommendations

Graded consensus recommendations were developed based on the considered judgment of the multi-disciplinary Task Force, which considered the volume and consistency of the evidence and the generalizability and clinical impact of the recommendations.

Rating Scheme for the Strength of the Recommendations

Grades of Recommendation

"Some" means the recommendation considered at least one adequate scientific study, which reported that a treatment was effective. The Division recognizes that further research is likely to have an impact on the intervention's effect.

"Good" means the recommendation considered the availability of multiple adequate scientific studies or at least one relevant high-quality scientific study, which reported that a treatment was effective. The Division recognizes that further research may have an impact on the intervention's effect.

"Strong" means the recommendation considered the availability of multiple relevant and high-quality scientific studies, which arrived at similar conclusions about the effectiveness of a treatment. The Division recognizes that further research is unlikely to have an important impact on the

intervention's effect.

Cost Analysis

The guideline developers reviewed published cost analyses.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

After the internal panel/task force draft is complete it goes to an extensive external expert panel for review and response.

Advisory Panel

The Guidelines update process includes an additional review, conducted by an Advisory Panel and other advisory bodies that may consist of past Task Force members and clinical experts representing medical specialty organizations and associations. Professionals representing adjunct aspects of patient care, such as Risk Managers, Case Managers, and Insurers, are also included in this stage. The purpose of the external review is to provide additional sources of expertise in order to finalize draft guideline material developed by the Task Force.

Solicitation of Public Commentary

An active, open process to solicit public commentary on a year-round basis is in place in order to maximize community-based physician input and support. Contact with Accredited Providers is done through direct mailings and at Accreditation seminars.

Post Task Force Questionnaire

A survey will be sent to all Task Force members once the updated draft guidelines are completed. The survey will rate Task Force participants' satisfaction with the processes used, and evaluate Division personnel and performance. Information may be used to improve future Task Force processes.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

Only randomized controlled trials or meta-analyses were used for evidence statements regarding treatment.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Optimal medical and functional outcomes for injured workers with low back pain

Potential Harms

- Injuries, side effects, or infections from therapeutic injections

- Side effects and drug interactions from medications
- Complications from operative procedures
- Injury from device or component failure

See specific sections of the original guideline document for detailed descriptions of potential harms.

Contraindications

Contraindications

- Magnetic resonance imaging (MRI) is contraindicated in patients with certain ferrous and other implants; however, MRI scanners compatible with pacemakers are now available.
- Computed tomography (CT) and MRI are contraindicated for morbidly obese patients or those who have undergone multiple surgical procedures.
- Absolute contraindications to therapeutic injections include: (a) bacterial infection – systemic or localized to region of injection, (b) bleeding diatheses, (c) hematological conditions, (d) pain of three points or less on a 10-point Visual Analog Scale (VAS) measurement at the time of injection, (e) possible pregnancy, and (f) poorly controlled diabetes mellitus for steroid injections. Relative contraindications to therapeutic injections may include: allergy to contrast, somatization disorders, poorly controlled congestive heart failure for steroid injections, risk factors for osteoporosis and uncontrolled hypertension.
- Contraindications to discography include: (a) active infection of any type or continuing antibiotic treatment for infection; (b) bleeding diathesis or pharmaceutical anticoagulation with warfarin, etc.; (c) significant spinal stenosis at the level being studied as visualized by MRI, myelography or CT scan; (d) presence of clinical myelopathy; (e) effacement of the cord, thecal sac or circumferential absence of epidural fat; and/or (f) known allergic reactions.
- Celecoxib is contraindicated in sulfonamide allergic patients.
- Contraindications to high velocity, low amplitude (HVLA) manipulation include joint instability, fractures, severe osteoporosis, infection, metastatic cancer, active inflammatory arthritides, aortic aneurysm, and signs of progressive neurologic deficits.
- Grade V mobilization contraindications include joint instability, fractures, severe osteoporosis, infection, metastatic cancer, active inflammatory arthritides, aortic aneurysm, and signs of progressive neurologic deficits.
- Manual traction is contraindicated in patients with tumor, infection, fracture, or fracture dislocation. Best practice suggests that this modality be accompanied by active therapy.
- The recombinant human bone morphogenetic protein-2 (rhBMP-2) used with the interbody fusion device is contraindicated for patients with a known hypersensitivity to rhBMP-2, bovine type 1 collagen, or to other components of the formulation.
- Contraindications to intraspinal spacers include anatomy that prevents implantation due to significant lumbar instability, ankylosis, acute fracture of the spinous process or pars interarticularis; allergy to titanium or titanium alloy; significant scoliosis; fixed motor deficit; cauda equina syndrome; neural compression causing neurogenic bowel or bladder dysfunction; previous lumbar surgery; significant peripheral neuropathy; spondylolisthesis greater than 1.0 (on a scale from 1-4) at the affected level; sustained pathological fractures; severe osteoporosis of the vertebrae or hips; severe foraminal stenosis; obesity; active infection or systemic disease; Paget's disease or metastasis to the vertebrae; steroid use for more than 1 month with 12 months preceding surgery. Relative contraindication: adjacent level disease.
- Contraindications to artificial lumbar disc replacement include significant spinal deformity/scoliosis; symptomatic facet joint arthrosis – If imaging findings and physical exam of pain on extension and lateral bending are present, exploration of facet originated pain should be completed prior to disc replacement; spinal instability at the pathologic or adjacent level requiring fusion; deficient posterior elements; infection; any contraindications to an anterior abdominal approach (including multiple prior abdominal procedures); evidence of nerve root compression, depending on the device used; previous compression or burst fracture; multiple-level degenerative disc disease (DDD); spinal canal stenosis; spondylolysis; spondylolisthesis greater than 3 mm; osteopenia, osteoporosis or any metabolic bone disease; chronic steroid use or use of other medication known to interfere with bone or soft tissue healing; allergy to device components/materials; depending on the device selected, pregnancy or desire to become pregnant; morbid obesity (e.g., body/mass index [BMI] of greater than 40, over 100 pounds overweight); active malignancy; generalized chronic pain.
- Contraindications to kyphoplasty include asymptomatic vertebral body compression fracture, patient improvement with medical treatment; the presence of neurologic compromise related to fracture, high-velocity fractures with a significant burst component; significant posterior vertebral body wall fracture; severe vertebral collapse (vertebra plana); infection; coagulopathy.
- Contraindications to vertebroplasty include asymptomatic vertebral body compression fracture; patient improvement with medical treatment; the presence of neurologic compromise related to the fracture; high velocity fractures with a significant burst component; posterior vertebral body wall fracture; severe vertebral collapse (vertebra plana); spinal canal stenosis; allergy to bone cement or opacification agents; active or

incompletely treated infection; uncorrectable coagulopathy.

Qualifying Statements

Qualifying Statements

- This document has been prepared by the Colorado Department of Labor and Employment, Division of Workers' Compensation (Division) and should be interpreted within the context of guidelines for physicians/providers treating individuals who qualify as injured workers with low back pain under Colorado's Workers' Compensation Act.
- Although the primary purposes of this document are advisory and educational, these guidelines are enforceable under the Workers' Compensation Rules of Procedure, 7 CCR 1101-3. The Division recognizes that acceptable medical practice may include deviations from these guidelines, as individual cases dictate. Therefore, these guidelines are not relevant as evidence of a provider's legal standard of professional care.
- To properly utilize this document, the reader should not skip nor overlook any sections.
- The Division provides procedures to implement medical treatment guidelines and to foster communication to resolve disputes among the provider, payer, and patient through the Workers' Compensation Rules of Procedure. In lieu of more costly litigation, parties may wish to seek administrative dispute resolution services through the Division or the Office of Administrative Courts.

Implementation of the Guideline

Description of Implementation Strategy

The principles summarized in this section are key to the intended implementation of all Division of Workers' Compensation guidelines and are critical to the reader's application of the guidelines in this document.

1. Application of Guidelines. The Division provides procedures to implement medical treatment guidelines and to foster communication to resolve disputes among the provider, payer, and patient through the Worker's Compensation Rules of Procedure. In lieu of more costly litigation, parties may wish to seek administrative dispute resolution services through the Division or the Office of Administrative Courts.
2. Education. Education of the patient and family, as well as the employer, insurer, policy makers and the community should be the primary emphasis in the treatment of chronic pain and disability. Currently, practitioners often think of education last, after medications, manual therapy, and surgery. Practitioners must implement strategies, to educate patients, employers, insurance systems, policy makers, and the community as a whole. An education-based paradigm should always start with inexpensive communication providing reassuring and evidence-based information to the patient. More in-depth patient education is currently a component of treatment regimens which employ functional restorative, preventive, and rehabilitative programs. No treatment plan is complete without addressing issues of individual and/or group patient education as a means of facilitating self-management of symptoms and prevention.
3. Informed Decision Making. Providers should implement informed decision making as a crucial element of a successful treatment plan. Patients, with the assistance of their health care practitioner, should identify their personal and professional functional goals of treatment at the first visit. Progress towards the individual's identified functional goals should be addressed by all members of the health care team at subsequent visits and throughout the established treatment plan. Nurse case managers, physical therapists, and other members of the health care team play an integral role in informed decision making and achievement of functional goals. Patient education and informed decision making should facilitate self-management of symptoms and prevention of further injury.
4. Treatment Parameter Duration. Time frames for specific interventions commence once treatments have been initiated, not on the date of injury. Patient compliance, as well as availability of services will impact duration of treatment. Clinical judgment may substantiate the need to accelerate or decelerate the time frames discussed in this document.
5. Active Interventions. Active interventions emphasizing patient responsibility, such as therapeutic exercise and/or functional treatment, are generally emphasized over passive modalities, especially as treatment progresses. Generally, passive interventions are viewed as a means to facilitate progress in an active rehabilitation program with concomitant attainment of objective functional gains.
6. Active Therapeutic Exercise Program. Exercise program goals should incorporate patient strength, endurance, flexibility, coordination, and education. This includes functional application in vocational or community settings.
7. Positive Patient Response. Positive results are defined primarily as functional gains that can be objectively measured. Objective functional gains include, but are not limited to, positional tolerances, range of motion (ROM), strength, endurance, activities of daily living (ADLs),

cognition, psychological behavior, and efficiency/velocity measures that can be quantified. Subjective reports of pain and function should be considered and given relative weight when the pain has anatomic and physiologic correlation. Anatomic correlation must be based on objective findings.

8. Re-evaluation of Treatment Every Three to Four Weeks. If a given treatment or modality is not producing positive results within three to four weeks, the treatment should be either modified or discontinued. Before discontinuing the treatment, the provider should have a detailed discussion with the patient to determine the reason for failure to produce positive results. Reconsideration of diagnosis should also occur in the event of poor response to a seemingly rational intervention.
9. Surgical Interventions. Surgery should be contemplated within the context of expected functional outcome and not purely for the purpose of pain relief. The concept of "cure" with respect to surgical treatment by itself is generally a misnomer. Clinical findings, clinical course, and diagnostic tests must be consistent in order to justify operative interventions. A comprehensive assimilation of these factors must lead to a specific diagnosis with positive identification of pathologic conditions.
10. Six-Month Time Frame. The prognosis drops precipitously for returning an injured worker to work once he/she has been temporarily totally disabled for more than six months. The emphasis within these guidelines is to move patients along a continuum of care and return to work within a six-month time frame, whenever possible. It is important to note that time frames may not be pertinent to injuries that do not involve work-time loss or are not occupationally related.
11. Return to Work. Return to work is therapeutic, assuming the work is not likely to aggravate the basic problem. The practitioner must provide specific written physical limitations, and the patient should never be released to work with non-specific and vague descriptions such as, "sedentary" or "light duty." The following physical limitations should be considered and modified as recommended: lifting, pushing, pulling, crouching, carrying, walking, using stairs, bending at the waist, awkward and/or sustained postures, tolerance for sitting or standing, hot and cold environments, repetitive motion tasks, sustained grip, tool usage, and vibration factors. Even if there is residual chronic pain, return to work is not usually contraindicated.
    The practitioner should understand all of the physical demands of the patient's job position before returning the patient to full duty and should request clarification of the patient's job duties. Clarification should be obtained from the employer or, if necessary, including, but not limited to, an occupational health nurse, occupational therapist, vocational rehabilitation specialist, or an industrial hygienist.

12. Delayed Recovery. Strongly consider a psychological evaluation, if not previously provided, as well as interdisciplinary rehabilitation and vocational goal setting, for those patients who are failing to make expected progress 6 to 12 weeks after an injury. The Division recognizes that, even despite optimal care, 3% to 10% of all industrially injured patients will not recover within the timelines outlined in this document. Such individuals may require treatments beyond the limits discussed within this document, but such treatment will require clear documentation by the authorized treating practitioner focusing on objective functional gains afforded by further treatment and impact on prognosis.
13. Guideline Recommendations and Inclusion of Medical Evidence. *All recommendations are based on available evidence and/or consensus judgment.* When possible, guideline recommendations will note the level of evidence supporting the treatment recommendation. It is generally recognized that early reports of a positive treatment effect are frequently weakened or overturned by subsequent research. When interpreting medical evidence statements in the guideline, the following apply:
    - Consensus means the judgment of experienced professionals based on general medical principles. Consensus recommendations are designated in the guideline as "generally well-accepted," "generally accepted," "acceptable/accepted," or "well-established."
    - "Some" means the recommendation considered at least one adequate scientific study, which reported that a treatment was effective. The Division recognizes that further research is likely to have an impact on the intervention's effect.
    - "Good" means the recommendation considered the availability of multiple adequate scientific studies or at least one relevant high-quality scientific study, which reported that a treatment was effective. The Division recognizes that further research may have an impact on the intervention's effect.
    - "Strong" means the recommendation considered the availability of multiple relevant and high-quality scientific studies, which arrived at similar conclusions about the effectiveness of a treatment. The Division recognizes that further research is unlikely to have an important impact on the intervention's effect.

    All recommendations in the guideline are considered to represent reasonable care in appropriately selected cases, irrespective of the level of evidence or consensus statement attached to them. Those procedures considered inappropriate, unreasonable, or unnecessary are designated in the guideline as "not recommended."

14. Care Beyond Maximum Medical Improvement (MMI). MMI should be declared when a patient's condition has plateaued to the point where the authorized treating physician no longer believes further medical intervention is likely to result in improved function. However, some patients may require treatment after MMI has been declared in order to maintain their functional state. The recommendations in this guideline are for pre-MMI care and are not intended to limit post-MMI treatment.

The guideline document should be interpreted within the parameters of these guidelines principles that may lead to more optimal medical and

functional outcomes for injured workers.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Colorado Division of Workers' Compensation. Low back pain medical treatment guidelines. Denver (CO): Colorado Division of Workers' Compensation; 2014 Feb 3. 112 p.

Adaptation

Not applicable: The guideline was not adapted from another source.

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Composition of Group That Authored the Guideline

Not stated

Financial Disclosures/Conflicts of Interest

Financial disclosures are on file.

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Electronic copies: Available from the Colorado Division of Workers' Compensation Web site .

Availability of Companion Documents

The following are available:

- Low back pain medical treatment guidelines. Referenced version. Denver (CO): Colorado Division of Workers' Compensation; 2014 Feb 3. 187 p. Electronic copies: Available from the Colorado Division of Workers' Compensation Web site .
- Search terms/general search topics. Denver (CO): Colorado Division of Workers' Compensation. 8 p. Electronic copies: Available from the Colorado Division of Workers' Compensation Web site .
- Evidence summary: low back pain medical treatment guidelines. Denver (CO): Colorado Division of Workers' Compensation. 35 p. Electronic copies: Available from the Colorado Division of Workers' Compensation Web site .
- General literature search strategy for medical treatment guidelines. Denver (CO): Colorado Division of Workers' Compensation. 1 p. Electronic copies: Available from the Colorado Division of Workers' Compensation Web site .
- Division of Workers' Compensation medical treatment guidelinesâ€methodology. Denver (CO): Colorado Division of Workers' Compensation. 10 p. Electronic copies: Available from the Colorado Division of Workers' Compensation Web site .

In addition, related critiques are available from the Colorado Division of Workers' Compensation Web site . Assessment criteria for critiques are also available from the Colorado Division of Workers' Compensation Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on April 10, 2015. The information was verified by the guideline developer on June 18, 2015. This summary was updated by ECRI Institute on September 21, 2015 following the U.S. Food and Drug Administration advisory on non-aspirin nonsteroidal anti-inflammatory drugs (NSAIDs). This summary was updated by ECRI Institute on June 2, 2016 following the U.S. Food and Drug Administration advisory on Opioid pain medicines.

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